MEDICAL TEXTILES

Proceedings of the International Conference 24 & 25 August 1999
Bolton UK

EDITED BY
Professor Subhash Anand
Bolton Institute, UK

HOSTED BY

Bolton Institute

Faculty of Technology (Textiles)

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PREFACE

It has been predicted that hygiene and medical textiles will account for 1.65 m tonnes or almost 12 per cent of the total worldwide technical textiles market of nearly 14 m tonnes in the year 2005. The sheer diversity of applications for medical textiles is nothing short of mind-blowing. Just some examples of these applications include textile structures made of polylactic acid and polyglycolic acid fibres, which are being used as structures for cell growth. Even human organic tissues like skin, cartilage, liver, pancreas and kidney can be grown on temporary bioresorbable textile supports.

In addition, smart fibres loaded with drugs and based on naturally occurring polymers, as well as non-animal-based protein fibres and structures, are also being developed for the treatment of wounds and ulcers. In short, the future potential of medical textiles could well mean unlimited growth.

In Europe, medical textiles are already 10 per cent of the technical textiles market, with 100 000 tonnes of fibre, a growth rate of 3 to 4 per cent per year and a market of US$ 7 billion.

Bolton Institute hosted its second International Conference in this area – Medical Textiles 99 – on 24 and 25 August 1999. The two-day conference attracted 170 delegates from most of the major countries worldwide. Twenty-eight papers were presented which covered modern materials and processes, compression and bandaging, healthcare and hygiene, woundcare, implantable devices and test methods. A poster session and an industrial exhibition also complemented the event.

I wish to extend special thanks to SSL International plc, Smith and Nephew Medical Fabrics Ltd, Vernon-Carus Ltd; Surgical Dressing Manufacturers Association (SDMA), Association of British Health-Care Industries (ABHI) and Lantor (UK) Ltd; for their generous sponsorship and cooperation; David Hill and Janet Galligan, Bolton Institute; Graham Collyer and Paul Gray, SSL International plc; Peter Banham, Smith and Nephew Medical Fabrics Ltd; and Rick Wiggans, Johnson & Johnson Medical Fabrics; for taking an active part in the conference organisation and managing their specific responsibilities efficiently. I also gratefully acknowledge the support and contributions from each of the respective authors and presenters for submitting and modifying their scripts for publication.

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October 2000

Session 1: Modern materials and processes

1. New Developments in the Manufacture of Circular Knitting Machines for the Production of Medical Textiles

S.P. Mermelstein and D. Hale

Tritex International and Loughborough University, UK

INTRODUCTION

The medical and Healthcare sectors are growing rapidly within the textile industry. This growth requires parallel developments in the medical products, the materials they are made of and technology to produce them. The aim of this paper is to review the recent developments and the potential of one of the areas of production: Circular knitting machines.

Tritex has been manufacturing circular knitting machines since 1979, and owes its success to the ability to build machines to the specific requirements of customers of any area of expertise. The wide range of customers and applications that this has provided has meant that we have been able to apply practices proven successful by customers in one industry to other industries, where they were unheard of.

Circular weft knitting machines have been used for many applications in the medical industry. This paper describes the development that has been carried out on weft knitting machines in order to produce specific medical products.

Traditionally warp knitted fabrics have been manufactured using large flat machines. The market for tubular fabrics, medical and other, is currently being covered by double needle bar machines. However, Tritex in conjunction with Loughborough University, are developing a range of circular warp knitting machines suited for medical textiles. The paper discusses the design concepts, the potential of this new development for the medical industry and the advantages that the new range will provide for those in the production of medical textiles as well as those developing them.

WEFT KNITTING DEVELOPMENTS

Weft knitting has been used mainly in the production of two medical product groups; namely support bandages and simple elastic ones. The former are manufactured using two sets of needles to achieve a ribbed structure, which has some elasticity in itself, and inlaying a covered rubber at a given ension, which will determine he level of compression of the bandage.

The latter are manufactured using a fabric produced with a single set of needles. Although an elastic yarn is also inlaid in

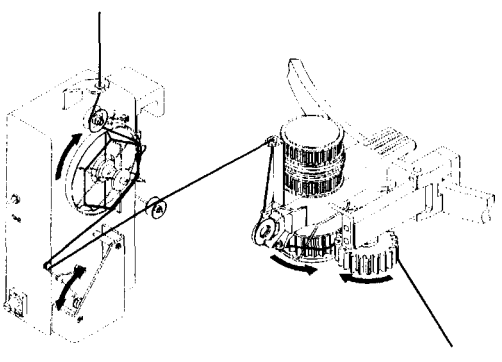

Figure 1. Elastic Positive Feed with Gears and EFS

this type of bandage, the extent to which tney can provide support is reduced due to the difference in the fabric structure.

The issues that have driven the machine development of both types differ greatly;

Rib Structure for Support Bandages.

Positive Feed

Controlling the tension of the elasticated yarn being inlaid in a compression bandage has always posed complications. In order to maintain a constant feed rate from the positive feed system to the knitting machine, the tension of the elastic yarn before it reaches the positive feed device must also be constant. This problem can be addressed in two ways; 1) the tension of the elastic yarn before the positive feed can be controlled by an Electronic Feed System (which is already produced for other textile applications). 2) Ensure that the elastic yarn is in its relaxed state (i.e. under no tension) before the positive feed system.

Different knitting machine manufacturers and users have adopted their preferred style. The first method for controlling the tension of an elastic yarn fed into a knitting machine involved trapping the yarn between the belt and pulley of the positive feed unit. The machine for which this system was devised used a positive feed system based on timing belts and pulley with a variable speed drive in the form of a Variable Diameter Quality (VDQ) wheel. The VDQ wheel drives a pulley on each feed providing automatic synchronisation of yarn to all feeders. The system was based on the principle that three or more turns of the yarn around a feed-wheel and under the driving belt were adequate to ensure absolutely slip proof positive feed. The turns of the yarn on the wheel are used as a reservoir of yarn between the cone and the feeder.

An addition to this elastic positive feed method involved running the rubber through plastic spur gears before going through the positive feed units. It ensured no elastic yarn slippage and allowed to have zero tension on the elastic before the positive feed.

Another design concept centred around feeding the elastic yarns directly from the packages by driving the elastic yarn package from a spring loaded rubber covered roller.

At present, elastic feed is achieved using an Electronic Feed System (EFS) unit to ensure constant tension, before the positive feed system. In addition, the positive feed traditional drum is replaced by spur gears, to guarantee there is no slippage in the feeding process. See Figure 1.

Shaping

Support bandages should emulate the shape of the body part they are acting on. Knee bandages, for instance will be more efficient and comfortable if tapered to allow for a larger diameter around the thigh. In order to achieve the desired taper, knitting machines allow the user to alter the amount of elastic yarn fed into the fabric gradually. The length of elastic fed in a given course determines the diameter of the fabric.

For this purpose, machines are equipped with electronic speed control of the positive feed unit used for the elastic yarn. The feed rate of the ground yarn remains constant throughout. To ensure consistency in the compression properties of the bandages, garments produced in a given machine will always be tapered in the same direction. Hence, there will always be a section of redundant fabric between one

garment and the next to allow the elastic feed rate to reach the value required for the start of a new garment.

Adjusting the compressibility of the bandage where they cover joints will also provide improved comfort for the user. Altering the fabric structure within a garment makes this possible. In areas like the inside of elbows and knees, for example, a less dense structure will allow the user to have the limbs in their natural relaxed positions without creating blood circulation problems or discomfort.

There is a great variety of structures used in support bandages. They require machines equipped with individual needle selection, colour striping, electronic cam control and/or devices to produce heel like shapes. Structures used in bandages are also often used in other textile applications. However, they are generally restricted to double jersey structures, due to their added compression strength.

The capabilities of the machine will reflect on the quality of the garment and hence, on its selling price. Flat weft knitting machines have traditionally been used for more complex, higher quality bandages due to the comparative ease of incorporating any additional features required. Moreover, the number of needles used can easily be adjusted within a garment being knitted in a flat machine.

Modified Single Jersey Elasticated Structures for Simple Elastic Bandages

The structure originally used to produce this type of bandage, namely single jersey with an elastic yarn inlaid into every other needle, was based on the use of different lengths of butt guided by a single track. Normal length butts extend into the cam-track and are guided by contact with their profiled edges. Shorter ones may not reach into the track and will pass across the face of the cam unaffected by its profile. This design, however, limits the speed of the machine. The cam used to drive the longer butt needles will create a void between the cam face and the needle stem allowing the needles to twist at high speeds.

The use of needles with multiple uniform length butt positions is therefore preferred for the application. This implies the use of more cam tracks in order to produce the same structure. This particular structure requires two tracks and the cam layout shown on Table 1. A similar structure is widely used for this application in a machine equipped with the first three cams.

Table 1. Cam Layout

	Cam 1	**Cam 2**	**Cam 3**	**Cam 4**	**Cam 5**	**Cam 6**
Butt Position 1	Knit	Tuck	Knit	Knit	Welt	Knit
Butt Position 2	Knit	Welt	Knit	Knit	Tuck	Knit

Wrap Striper

A further development has been carried out for this type of bandage structure to allow for size identification by means of adding a vertical coloured wale. A vertical line in a weft knitted fabric cannot be created using standard weft structures. The coloured wale requires a yarn to be provided to the same needle at each course.

In the 1970's Moorgate developed a gear driven mechanism for this purpose. It involved driving a striper finger with a reciprocating part-gear that would stop rotating when it struck a stop pin. This method, although successful, produced a great deal of noise and wear.

Tritex designed an alternative solution in the mid 1990's using a cam-track to continuously feed a coloured yarn to the same needle. On the final design, the coloured yarn is always wrapped around the needle in the same direction to ensure the stitches are visually consistent with the rest of the fabric. The cam profile is designed so that the coloured yarn feeder returned to the correct position to wrap over the needle in the right direction.

Later, Harry Lucas Gmbh. came up with a solution similar to the initial Moorgate one to achieve the same results.

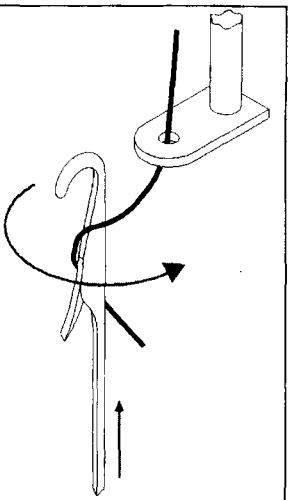

Figure 2. Wrap Striping Concept[1]

Potential Developments

Broken Hook Detector.

Weft knitted applications have always benefited from developments carried out for other markets. One such innovation, a broken hook detector, originally designed for wire knitting machines can prove very useful in preventing faults in medical textiles. The concept has now been used by another manufacturer for a textile application.

The detector developed by Tritex is based on the matching of two proximity signals. The first, produced by the needle hook, is compared with another created by a castellated disc. See Figure 3. Broken Hook Detector Concept. The disc indicates the position of each needle within the cylinder. A broken hook will result in the absence of one of the signals and halt the machine.

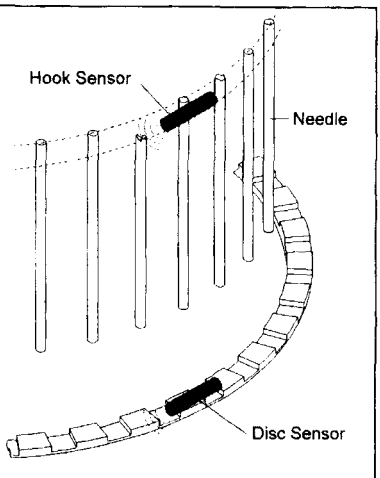

Figure 3. Broken Hook Detector Concept.

This is particularly useful for medical textiles where quality needs to be closely monitored and elastic yarns create higher tension in the fabric. Broken elements from a knitting machine, if undetected, could find their way into the fabric and ultimately the patient's skin

EFS Comparing Card

Electronic Feed System units have long been used in many knitting applications to ensure consistent yarn tension in a given feed. An electronic device has been developed enabling to compare the tension provided by

up to nine EFS units, and hence ensuring consistency across the knitting machine. This concept could be applied to machines used for medical bandages with a view to improving the existing positive feed.

CIRCULAR WARP KNITTING DEVELOPMENTS

Warp knitting has been used as a manufacturing method for medical products, mainly in the fields of wound dressing, bandages and vascular grafts[i]. Weft inserted warp knitted structures have also been used in the medical industry; dialysis filters are an example[ii]. Although all of these products are tubular, only gauze retention nets are being produced on circular machines. This is mainly due to the limitations of the circular machines available and the imbalance between development time on flat and circular machines.

Knitting Mechanism

The main differences between circular warp knitting machine designs centre around the knitting mechanism. Within European and British patent applications, there are only two filed for circular warp knitting machines. The first one, filed by an Israeli company in 1986, is a design for a circular warp knitting machine with two patterning rings, introducing an innovative way to make a stitch[iii]. The motor drive makes a plastic sleeve inside the needle cylinder reciprocate vertically, while the needles remain stationary. The sleeve moves the knitted fabric with it. The movement of the fabric, rather than the needles, produces the stitch. Tritex NE150 model, although not patented, used a similar mechanism.

The second patent application[iv] is also for a machine with two patterning rings. Its main improvements are a set of radially moving sinkers and thread guide elements (also radially moving) located in the tricks of two patterning rings concentrically arranged. See Figure 4.

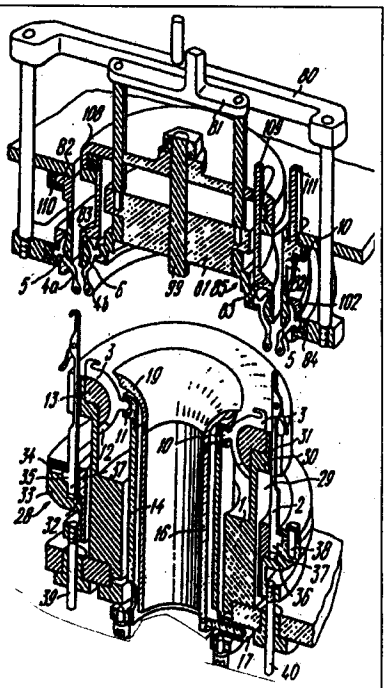

Figure 4. Patent Application

Another design used mainly in the stockings industry, Moorgate model 218, used an eccentric drive for the needle reciprocation and cams for the patterning.

Circular warp knitting machines adopted the use of a tricked cylinder from weft knitting machine manufacturers to use as a guide for the needles' vertical motion. On a circular warp machine, however, this restricts the ability of the machine to produce long underlaps.

The loop formation cycle on a flat warp knitting machine is a combination of vertical motion of the needles with shogging and swinging of the guide bars in two perpendicular planes.

Circular machines have relied on their geometry to remove the necessity to perform the swinging motion. The shogging action is achieved by rotating the patterning rings. The

use of a conical needle bed (see Figure 5), instead of the traditional cylinder, introduces the swing action of a flat machine guide bar to circular machines for the first time; combining it with the reciprocating motion of the needles in a single move.

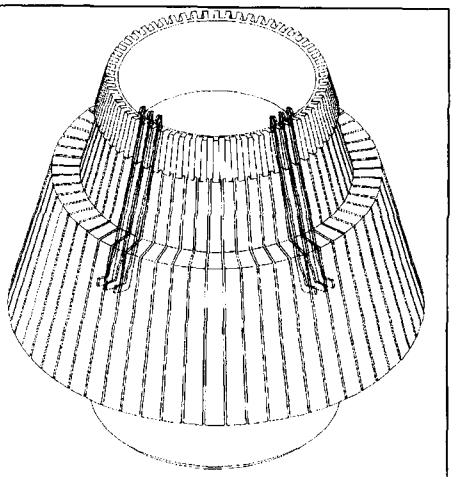

Figure 5. Conical Needle Bed

Fabric Structures and Patterning Mechanisms

For many years, the only circular warp Knitting machines available were equipped with two patterning rings controlled via cams. Six and eight-course repeat patterns were the norm for this type of machine. However, some are capable of up to twelve-course repeat designs.

There is currently only one range of medical products, gauze retention, knitted on circular warp machines. This is due to the simplicity of their structure; manufactured using two fully threaded patterning rings (See Figure 6) knitting over two adjacent needles.

A substantial percentage of medical products require a tubular fabric. At present they are manufactured on double-needle bar Raschel machines equipped with a large number of patterning bars. The drawback of producing tubular fabrics on these machines is that for each pattern chain required to complete the fabric structure, two bars need to be dedicated to the production of the sides of the tube, and extra bars are necessary to produce the seams. A circular machine's patterning ring will therefore effectively replace at least three double needle patterning bars. In order to produce a greater variety of medical products on a circular warp machine, a new design with more than two patterning rings was necessary.

The latest development went further, incorporating full electronic control of up to Three patterning rings. This allows for maximum flexibility in pattern design and almost unlimited pattern length. The only restriction in the pattern length being the memory of the computer used. The electronics can be programmed via a Personal Computer to give instructions for one or a number of fabric structures. In this way maximum pattern flexibility is offered, since there is no need for a special cam for each structure.

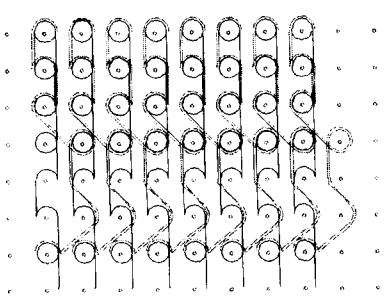

Figure 6. Gauze Retention Structure.

Electronic control of the patterning will also allow for fabric shaping by altering the diameter of the fabric tube produced. This can be

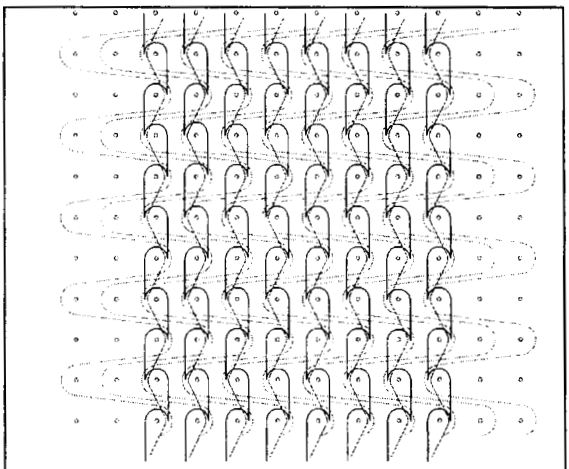

Figure 7. Flat Warp Knitted Bandage Structure

accomplished by modifying the structure of the fabric within a garment whilst keeping the stitch length unchanged. Fabric shaping can also be varied by adjusting the stitch length.

Research is being conducted With Loughborough University to establish the optimum machine configuration to achieve maximum underlap capability. The objective of the study is to create a set of equations to predict the intersection of a thread after a shog displacement with a target needle (the needle on which the next stitch is to be produced), and thus investigate different values of cone taper, patterning ring diameter, vertical separation of rings and needles and shog amplitude.

In bandage applications, the extensibility of the fabric in a given plane is an important parameter. It is generally determined by the pattern chain the elastic yarn is following and it can be adjusted by altering the length of the underlap used and/or the fabric stitch length. Figure 7 shows an example of a warp knitted bandage The vertical and horizontal elastic inlaying will produce extensibility in both directions.

Other medical applications where tubular warp knitted fabrics have proved successful but have not been produced in circular machines include vascular and other type of arterial prostheses. Many researchers have compared the performance of warp knitted (using a plain or double velour pattern) with woven grafts (HAVERICH[v], 1984, ALIMI[vi], 1994, QUARMBY[vii], 1998 among others). Others have compared the different materials used in warp and weft knitted grafts including polyester, PTFE and Dacron with and without coatings (JONAS[viii],1986, GUIDOIN[ix], 1997).However, there is very little published on alternative manufacturing methods. These are potential applications for the new circular warp knitting machine.

Another possible application for circular warp knitted medical products might be in developing an alternative to the weft knitted stockings currently used to provide pressure gradients along the leg after surgery, aiding blood circulation. The different compression levels can be built in the pattern design.

Let-Off Mechanism

Despite the benefits of positive let-off proven by flat knitting machine manufacturers, circular machine designs relied on the takedown to govern the fabric quality. Flat machines let-off mechanisms have evolved from the simplest ones releasing yarn on demand from the needles and controlled only by weights on a rope, acting as the brake. Its simplicity, however, is outweighed by the need for periodical removal of the weights,. In addition, it produces a high average tension making it difficult to handle weak yarns at high speeds.

Other versions of tension controlled let-off mechanisms followed. They included intermittent drives based on an expanding brake control and variable speed designs - mechanical, hydraulic and electrical -, that relied on a tension bar to dictate the speed of the warp beam. Tension let-off mechanisms, however, have several drawbacks; firstly there was difficulty in obtaining a satisfactory average tension across the warp sheet. Secondly, it relies on the consistency of the warping tension. Finally, it is affected by the tension variation within the loop forming cycle.

Designers, therefore, turned to speed controlled systems, which involved yarn speed monitoring mechanisms and variable drive to the beam. Tritex circular warp knitting machines are fed directly from cones on creels, and have positive let-off, to ensure consistent quality of the fabric.

As with weft knitted medical products designed to fit various parts of the human body, a shaped tubular warp knitted fabric will perform better. Electronic stitch length control enables the production of different diameter fabric, whilst maintaining the structure, within a garment. This feature was pioneered on the latest Tritex machine.

Nets in particular will benefit from this innovation, since longer stitches will create larger openings in the net. In these structures the length of the stitch is the only parameter determining the fabric diameter produced using a given number of needles.

Stitch length adjustment is performed by simultaneously changing the yarn feed rate and the fabric takedown velocity. This ensures that the amount of yarn supplied by the let-off will be drawn by the takedown and therefore overall yarn tension will remain balanced.

CONCLUSION

The creative process behind a new product is generally constrained by the technology available. To develop new technology for the manufacture of a new product (whatever the area of application), is often too expensive or too risky and therefore scientists prefer to find a less than optimum solution using the technology offered by industrialists. It is important, therefore, to create communication channels to allow scientists to understand the possibilities of technology, in order to achieve a suitable solution, as well as ensuring that industrialists understand the scientists needs. The new circular warp knitting machine development as well as the weft knitting modifications for medical applications are, we believe, the result of a better understanding of the market and its needs.

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[i] A J Rigby, S C Anand, A R Horrocks, 'Textile Materials for Medical and Healthcare Applications', J. Text. Inst., 1997, **88 Part 3**, 83-93.

[ii] S Raz, *Warp Knitting Production*, Heidelberg, Germany, Heidelberger Verlagsanatalt und Druckerei GmbH, 1987.

[iii] M Borenstein, Rundstrickmaschine, European Patent Application, Pat No. 0 200 094, Filed 05.11.86 Tel Aviv, Israel.

[iv] I Vyacheslavovich Ragosa, Circular Warp Knitting Machine, UK Patent Application, No. 2 039 544 A, 20 November, 1990.

[v] A Haverich, H Oelert, W Maatz, H G Borst, 'Histopatological evaluation of woven and knitted Dacron grafts for right ventricular conduits: a comparative experimental study.' Ann Thorac Surg, 1984 May **37:5** 404-11.

[vi] Y Alimi , C Juhan, N Morati, N Girard, S Cohen, 'Dilation of woven and knitted aortic prosthetic grafts: CT evaluation.' Ann Thorac Surg, 1994 May **8:3** 238-42.

[vii] J W Quarmby, K G Burnand, S J Lockhart, A E Donald, K M Sommervile, C W Jamieson, N L Browse. Br J Surg, 1998 Jun **85:6** 775-7

[viii] R A Jonas, F J Schoen, R J Levy, A R Castañeda, 'Biological sealants and knitted Dacron: porosity and histological comparisons of vascular graft materials with and without collagen and fibrin glue penetrants.' Ann Thorac Surg, 1986 Jun **41:6** 657-63.

[ix] R Guidoin, M King, Y Marois, P Ukpabi, X Deng, Z Zhang, C Yang, B Badour, G Laroche, L Martin, 'Polyester arterial prostheses, recent developments from the Czech Republic and Poland'. ASAIO J, 1997 Jan-Feb **43:1** 69-83.

2. Nonwovens – The choice for the Medical Industry into the Next Millennium

I. V. Walker

Lantor (UK) Ltd, UK

In modern healthcare, the demand for highest performance at minimal cost has enabled nonwovens to find increasing use and scope of applications.

Nonwovens have been used for many years in hospitals and clinics. These traditional and recognised uses for nonwovens include:
Operating room apparel, Sterilization wrap/packaging, Cleaning materials, Disposable bedding, Incontinence products, Wound dressings, Bandages.

However, there are other, and less obvious, uses for nonwovens in healthcare.

Filtration	-	Liquid, eg blood, body fluids, water
	-	Air, HVAC for O.R. and other, areas of clinical significance
	-	Anaesthetic gases
	-	Odour removal, Wound dressings, Ostomy
	-	Anti allergy bedding
Apparel	-	Disposable patient gowns, shrouds
	-	Reusable – components of uniforms etc.
	-	Components of shoes/footwear
Building	-	Insulation – sound, heat
	-	Flame retardant materials
	-	Components of furniture
	-	Carpets

Why are nonwovens so successful in meeting the demands of the healthcare provider?

In my opinion it is that nonwovens can be designed to meet the huge variety of needs in a very cost efficient manner.

Before it is possible to understand the scope of nonwoven materials, it is important to define the word 'Nonwoven'.

Definition

The definition of a nonwoven supported by European Disposable and Nonwoven Association (EDANA) is:-

"Nonwoven is a manufactured sheet of directionally or randomly oriented fibres, bonded by friction and/or cohesion and/or adhesion, excluding paper and products which are woven, knitted, tufted, stitch bonded incorporating binding yarns or filaments or felted by wet milling whether additionally needled or not. The fibres may be staple or continuous filament or be formed "in situ."

Nonwoven materials have an ability to be engineered to provide very special and sometimes unique properties that makes them so effective for healthcare applications.The

nonwoven process is also relatively simple compared to the traditional textile technologies of knitting and weaving.

Nonwovens technology allows for continuous production with minimal intermediate stages whilst the traditional textiles may require several distinct discontinuous batch processes e.g. spinning, winding, beaming, sizing before knitting or weaving.

In comparison with traditional textile technologies, the process is:-

Simple
Productive
Versatile
Economic
Innovative

The key reasons for the increase in demand for nonwovens and composites containing nonwovens are versatility, innovation and economic.

The Nonwoven Process

Nonwoven production consists of two basic stages

1) Formation of fibrous web.
2) Binding of fibres.

Nonwoven Web Formation

The web may be formed from cut staple fibres either by dry laying e.g. carding/air laying, wet laying; or direct polymer extrusion of continuos filament, e.g. spunlaid or melt blown.

Nonwoven Bonding

After formation of the web, further additional methods of web consolidation are usually required.

Mechanical

Fibre entanglement by barbed needles or water jets by physical means only. Mechanical bonding has very little effect upon the inherent fibre properties and can produce 100% fibre materials.

It is also possible to incorporate other materials e.g. scrims, wood pulp into the structure of the nonwoven.

Chemical

Impregnation, printing, spraying, with a suitable chemical followed by drying and further heating to "fix" the chemical reagent especially at fibre "cross over" points and achieve bonding. Chemicals depending upon their nature can be applied as a dilute aqueous dispersion, foam, paste or in organic solvents.

Organic solvent may also be used to partially soften certain polymer types and upon removal of the solvent form a bond.

Chemical bonding is extremely versatile and can be used to impart a number of different properties, e.g. water repellency, flame retardency, antistatic, colour and can also reduce propensity for linting/dusting.

Thermal

The use of thermoplastic materials in the web followed by heating the web until this material melts and bonds to other fibres upon cooling.

The heat application can be by hot calendar (flat or patterned), hot air, or other methods e.g. ultrasonic.

The advantages of this method are 100% fibre products can be produced cleanly and simply.

Each bonding process has its own particular advantage depending upon properties required and combination of any of the outlined methods are possible.

Fibres for Nonwovens

Fibres are the main raw material for nonwovens representing usually 70-100% of the total weight of the final product.

A large variety of polymers are available to nonwoven manufacturers which are derived from many sources, some are natural e.g. cotton, hemp, jute and others derived from natural sources (e.g. viscose, cellulose acetate, lyocell) and others are totally synthetic.

The polymer range covers absorbent cellulosic fibres, (e.g. cotton, viscose and modified viscose) through to non-absorbent synthetics (e.g. polyester, polypropylene, polyamide, acrylics, aramid, carbon and PTFE).

The range also includes more specialist polymers e.g. alginate, super absorbent, bicomponent, water soluble, electrostatic, metal, biodegradable.

Fibres of individual polymer types also have different physical attributes that can be used to produce different nonwoven properties.

Examples of modifiable fibre attributes include – length (very short to continuous filaments), diameter (very fine to very coarse), cross section, (hollow, multilobal), crimp (straight to highly crimped or heliced), splittable/fibrillating, colour, incorporation of other materials e.g. antimicrobials, flame retardants.

The fibres can have finish applied which can change their very nature, i.e. an absorbent viscose fibre can be made hydrophobic whilst a hydrophobic polypropylene fibre can be made hydrophillic.

In many cases one fibre alone cannot provide the desired performance hence several fibres may need to be blended to achieve optimum results.

The above is also a quick look at the fibre potential which in conjunction with nonwoven processes, highlights again the versatile potential of nonwoven materials.

Chemical for Nonwovens

I briefly described the nonwoven chemical bonding process for nonwovens and stated that different bonding methods could be used to complement each other.

Chemical finishes can also be applied to a nonwoven material produced by any of the above processes.

The finishes can be applied by numerous methods, (impregnation, printing. spraying, coating).

The finish can be applied through the structure or on one surface creating a two-sided material.

The range of chemicals that can be applied is vast, and the resultant range of properties is large.

Chemical agents can be added that may modify the handle, rigidity, abrasiveness. They may impart absorbency or repellency, add colour, flame retardant or antistatic properties. We can add activated carbon, zeolites, for odour control, antimicrobials, coatings for barrier properties, slip control, adhesion (pressure sensitive, thermoplastic), cohesion, microspheres to increase volume, or to incorporate perfumes and other potential additives.

Again, the chemicals used in conjunction with fibres and nonwoven processes give rise to a hugely versatile technology.

Properties

Having very briefly looked at the raw materials and manufacturing methods, we can now look at nonwoven properties and their relevance to healthcare.

Weight

Very light weight 5-15g/m^2 materials are used as coverstock, surfacing tissues, transmission, barrier, or wicking layers in composites. These products can be relatively strong but unobtrustive.

Heavier nonwovens are used in absorbent dressings, incontinence use, insulation and filtration.

Strength

Can be varied from strong fabrics (e.g. slings) to relatively weak and readily tearable applications (e.g. padding bandages).

Elongation/Stretch

Low elongation materials are required for filtration and protection,whilst elasticated high elongation and recovery for support and retention.

Handle

Very soft handle for skin contact applications to very harsh abrasive for scouring/cleaning uses.

Loft

Thin, unobtrusive cover stock layers to thicker materials for mechanical protection , thermal and acoustic insulation and coarse filtration.

Conformability

Very conformable dressings, bandages, drapes etc to very stiff or rigid materials e.g. curtain tie backs, chefs' hats.

Absorbency

The absorbency properties of nonwoven fabrics can be designed to give a wide range of absorbency or wetting properties.

Absorbency/Wetting Properties – Options

Absorb large quantities of liquid.
Absorb liquid quickly or slowly.
Retain liquid or transmit.
Wick liquid from one area to another.
Not absorb any liquid i.e. repel liquid.
Absorb some liquids e.g. oils, repel others e.g. water, or vice versa.

Liquids to be handled

Water, saline, urine, blood, wound exudate, menstrual fluid, alcohol.

Thermal Insulation

Good thermal insulation is usually achieved by entrapment of air into a structure. This is very readily achieved in nonwovens. Thermal insulation is an important characteristic for wound dressing where heat loss is a recognised problem.

Filtration properties

Very coarse filtration to remove large particles with low pressure loss to very fine particulate and sterilizing filters.

Composite structures can also be produced by combining different nonwovens to produce the ultimate filter in one unit e.g. face mask filter.

The particulate filter can be enhanced by the use of electrostatic fibres and the addition of different finishes.

One problem encountered by a large number of patients with either – surgically created stoma or infected wound, is odour.

This affects the patients self esteem and can make a difficult clinical situation much worse, for the patient.

Activated carbon can adsorb the molecules that are detected by the human nose as an unpleasant odour.

The use of activated carbon materials in wound dressings or covers and ostomy filtration has helped to reduce this problem and development of these systems continues.

Activated carbon is used in face masks in certain circumstances for the removal of unpleasant or irritating materials e.g. ammonia, acid gas. This property has been brought into the hospital environment and incorporated into air filtration for patients with special clinical requirements.

Another important characteristic in certain filtration applications is to achieve a tight "fit" to allow a good seal of filter to the unit, which requires protection by a filter. - Nonwovens can be thermally moulded to give large surface areas and achieve good fit (e.g. shaped facemasks, vacuum cleaner filters) to maximise protection.

Appearance

Although not of prime importance in technical applications, healthcare providers and patients are human and prefer to use/wear materials that are aesthetically pleasant.

Nonwovens can be apertured, coloured, printed, embossed to provide the aesthetics desired or for identification e.g. of different clinical area, or consultant, may have different coloured materials, wound dressing may have different coloured back etc.

It may also be important for "new" materials to look similar to those currently used in order to gain fast, widespread acceptance.

Composites

As healthcare requirements become increasingly demanding, it is apparent that one individual material may not be able to satisfy the end user, and that a composite of different properties is required.

Composite can combine the individual function of the various nonwoven materials, not only with other nonwoven fabrics but also with a large number of other materials.

The properties of all these materials can be combined to complement each other and produce a composite product that could not be achieved by a single material.

Nonwovens are the ideal materials with the appropriate properties to be incorporated into multilayer composites.

Nonwovens can provide

- Coverstock layer for transmission, wicking, low adherence.
- Wound contact layer - that can interact with the wound to form a gel.
- Padding layers - Absorbency, super absorbency
  - Thermal/mechanical insulation and protection
- Barrier Layers - Prevention of liquid bacterial strike through.

- Carrier layers for other materials
  - Super absorbent powders
  - Activated carbon
  - Antimicrobials
  - Adhesives
  - Microspheres

- Extensibility/elasticity
- Mouldability.

One example of a composite nonwoven product is an "Ideal Wound Dressing". The ideal dressing requirements are:

1. to maintain high humidity @ wound/dressing interface;
2. to remove excess exudates;
3. to allow gaseous exchange;
4. to provide thermal insulation and mechanical protection;
5. to be impermeable to bacteria;
6. to be free of particles and toxic wound contaminants; and
7. to allow removal without causing Trauma.

The requirements for the ideal dressing may be obtained by using nonwoven materials combined with other technologies (see Figure 1)

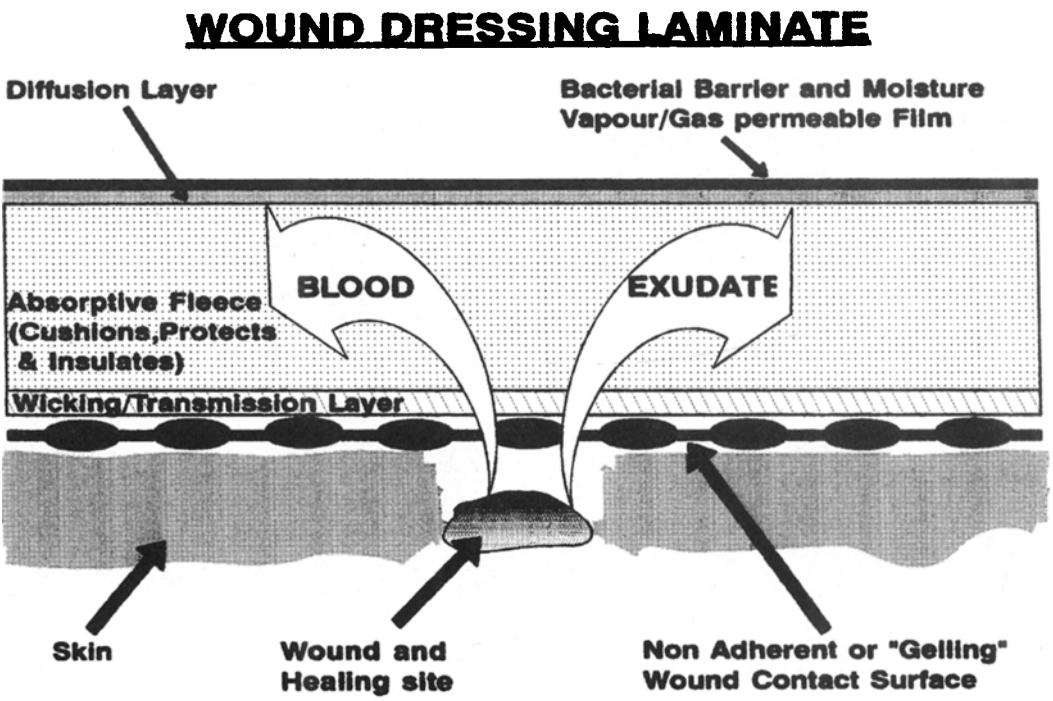

Figure 1

1. High humidity at the wound surface can be maintained by the use of a moisture vapour permeable film backing and / or a "gelling" wound contact layer.
2. Excess exudate may be removed by the absorptive fleece and may be enchanced by the use of wicking or diffusion layers.
3. Gaseous exchange can be achieved by the choice of backing layers
4. Thermal insulation and mechanical protection as provided by the choice of absorptive fleece and backing materials.
5. Impermeability to bacteria is recognized as a property of most "dry" dressings. Bacteria usually require strike through of either wound exudate or liquid from/to the back or edge of the dressing to the wound. Layers which resist this strike through can assist in increasing the time to strike through, however the most effective barrier is a pin hole free film, preferably moisture vapour and "gas" permeable.
6. To be free of particles and toxic contaminants. The materials used in wound dressings are required to be nontoxic to the wound and with the use of a combination of technologies the particles can be minimised. Interactive dressing materials may leave a "gel" which can be gently irrigated to remove any residues.
7. The removal of dressings without trauma has been the desire of clinicians for a long time. The development of low adherent materials, polymers which "gel" in contact with wound exudate and the careful choice of dressing types by clinicians has reduced the trauma upon removal significantly.

Summary

This very brief overview of technologies, raw materials and properties is designed to illustrate how versatile and economic nonwoven materials are. This is why they are, and will continue to be, the choice for the medical industry into the next Millennium.

3. Production of Yarns and Fabrics from Alginate Fibres for Medical Applications

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Abstract

It has been widely accepted that alginate nonwoven wound dressings are advantageous over traditional dressings in wound healing. However, the fact that the alginate fibres gel when having absorbed body exudate makes it difficult to remove the dressings from wounds, this being especially true for cavity wounds. This paper explains the development of the reinforced wound dressings and discusses the absorbency of such dressings.

1. Introduction

As one of the new hightech products for medical applications, alginate wound dressings have been widely accepted and used in hospitals and clinics to facilitate "moist wound healing". Alginate is a substance existing in brown seaweed. It is a high molecular-weight polymer which is essential for fibre formation. The polymer is associated with interchangeable cations which influence the polymer properties. Typically, sodium alginate is water soluble and calcium alginate is not. A mixed sodium and calcium alginate shows intermediate behaviour by absorbing water and swelling to form a gel. Based on this principle, calcium alginate will gel in a fluid, such as wound exudate, containing sodium ions. Alginate polymer contains two building units, i.e. mannuronic acid (M) and the guluronic acid (G). In practice, fibres made from alginate polymer contain either a high proportion of G or of M units. In high G alginate fibres, the calcium ions are firmly bound and consequently the fibre is slower to gel because of the low rate of ion exchange. High M alginate fibres, on the other hand, are quicker to gel due to the loose bond of the calcium ions to the fibre structure. To accommodate different dressing requirements, both high M and high G alginate wound dressings are commercially available in the market.

Most of the alginate wound dressings are made in the form of a nonwoven fabric for flat wounds, or of a sliver (rope) for cavity wounds. Alginate wound dressings are mostly used for wounds with moderate to heavy wound exudate, and therefore absorbency is an important parameter. Another desirable aspect is that the gelled dressings should maintain a suitable strength so that they can be removed easily after use. However, gel strength is generally poor due to swelling of the absorbent fibres. In practice, the removal of gelled alginate dressings is often enabled by an excess of sodium ions provided by irrigation solutions. This can be messy and quite awkward for some type of wounds, especially the cavity wounds.

The objective of this paper is to investigate the possibility of developing a new type of alginate wound dressing that would be absorbent in use and easy to remove afterwards. This paper introduces the concept of reinforced wound dressings and reports on the production of reinforced alginate yarns and fabrics for wound dressing applications.

2. The Concept of Reinforced Wound Dressings

In their current forms, alginate wound dressings change to gel due to the uptake of the wound exudate, when the fibre structure disintegrates and the dressings lose their strength. In many situations, a used alginate dressing can not be removed in one piece.

Reinforced wound dressings refer to the type of alginate dressings that contain a web of continuous non-gelling materials, which, when the dressings are wetted, will act as a bone structure to the dressings to facilitate a complete and clean removal. Clinically acceptable filament could be used as the web forming material, and the web can be generated using different methods, such as weaving, braiding and knitting.

3. Development of Reinforced Alginate Yarns

Table 1 lists the tenacity and extension of some of the commonly used textile fibres and, for contrast, those of the alginate fibre[1][2].

Table 1

Fibre	Tenacity (cN/tex)	Elongation (%)
Cotton	26.5 – 44.1	5 - 10
Wool	8.8 – 15.0	25 - 35
Polyester	35.3 – 44.1	30 - 50
Nylon 6,6	36.2 – 39.7	37 - 40
Alginate	***14.0 – 18.0***	***2 - 6***

Table 1 shows that cotton fibres are of high tenacity and low elongation, wool of low tenacity and high elongation, and polyester and nylon high tenacity and high elongation. Fibre processes are available for cotton or cotton-like fibres and wool and wool-like fibres. It is evident from Table 1 that the alginate fibres, compared to the other listed fibres, have low tenacity and low elongation. This means that it is difficult for the alginate fibre to go through either the cotton process or the wool processes. Therefore, a specially arranged process is needed for making yarns from the alginate fibre.

3.1 The carding process

Carding is one of the most important operations in staple yarn making. It separates the tufts into individual fibres, removes short fibres and trash particles, and orients fibres length-wise to form the carded sliver. In the presented research, a carding system suitable for worsted carding, was used for carding the alginate fibres. The alginate fibres received for carding were opened with effective length being 66 mm and the short fibre content 57.7%. The carding parameters were optimised for the effective fibre length and short fibre content in the carded sliver. It was found that fibre input load, ratio of surface speeds of the feed roller and the take-in roller, the fibre regain all affect the carded sliver quality. For example, an input load of 312.5 – 416.7 g/m^2 relates to the best carded slivers, where the effective fibre length is between 42.0 to 43.5 mm and the short fibre content is between 76.5 to 77%.

3.2 The drawing process

Drawing combines a number of carded slivers and forms a single drawn sliver by drafting. The main purposes of the drawing process are to orient the fibres in the sliver and to increase the sliver evenness by mixing the fibres, apart from others. A RIETER draw frame was used for drawing the alginate slivers. The number of doublings, draft, and draft zones were experimented upon and the best setting were achieved for processing the alginate sliver. For the alginate fibres processed, it was found that doubling 6 carded slivers of about 3.2 g/m produced the best drawn sliver at a draft of 6.93. The draw sliver produced had a linear density of 2.7 g/m, with an effective fibre length of 38.5 mm and short fibre content of 65.5%. It was also found that allowing too much fibre going through the drawing nozzle produced hard lumps in the sliver, which is unusable. In this research, most of alginate yarns were made directly from the drawn sliver in order to reduce the processing cost.

3.3 The roving process

Roving was used for making finer alginate yarns. While the drawing process improves the parallelism of fibre within the sliver, the inter-fibre cohesion is reduced and so is the sliver strength. The roving process is to insert an adequate level of twist into the sliver to increase strength, and, at the same time, to reduce the thickness of the sliver so that it is suitable for spinning. A Plat Saco Lowell Rovematic roving frame was used for roving. One set of parameters was used for roving. The twist level inserted was 44 turns/m and the draft was set to 7.4. 2 slivers were used for doubling. The effective fibre length was further reduced by about 5%. However, it showed a better spinnability than the draw slivers.

3.4 The making of reinforced alginate yarns

In order to make reinforced fabrics for dressings, a reinforced yarn was required. The reinforced yarn should hold the alginate fibres loosely for maximum absorbency and also provide suitable strength to facilitate the removal of dressings. The gimp yarn structure was selected as it meets the requirements. A gimp yarn is composed of three components, the core, the sheath, and the binder. In this research, clinically acceptable filament yarns were used for both the core and binder, and the alginate fibres, in the form of either a twistless drawn sliver or a slightly twisted roving, were used as the sheath in the structure.

GDM Mk2, a hollow spindle machine for making fancy yarns, was employed for the making of the alginate gimp yarns. The objective was to make alginate gimp yarns of different thickness with reasonable regularity. It was found that the sliver/roving quality is of primary importance in the yarn making. If the effective length of alginate fibres is low or if there is a high short fibre content, then there would be problems in the yarn making process. The most serious problem is that the flow of alginate fibres becomes discontinuous in the gimp yarn – it firstly forms a slub then following it a thin place which contains only the core and the binder. This was the case when the drawn sliver of 3.7 g/m (effective length 25.5 mm, short fibre content 75%) was used for spinning. The slubbing problem limited the yarn delivery speed to 5 m/min, which is about one tenth of the normal machine speed. Fig. 1 shows the appearance of a yarn with slubs and thin places.

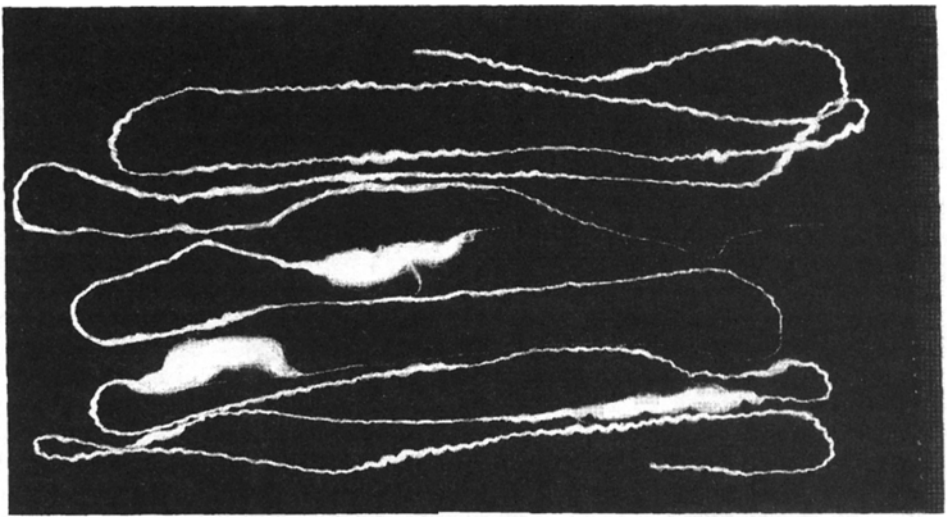


Fig. 1 Appearance of a yarn with slubs and thin places

Slubbing in the gimp yarn was found to be significantly reduced when the drawn sliver or roving has a reasonably high quality. In the experiment, the drawn sliver of 2.7 g/m and roving of 0.7 g/m led to gimp yarns of a much better quality. Fig. 2 shows the appearance of such a yarn.

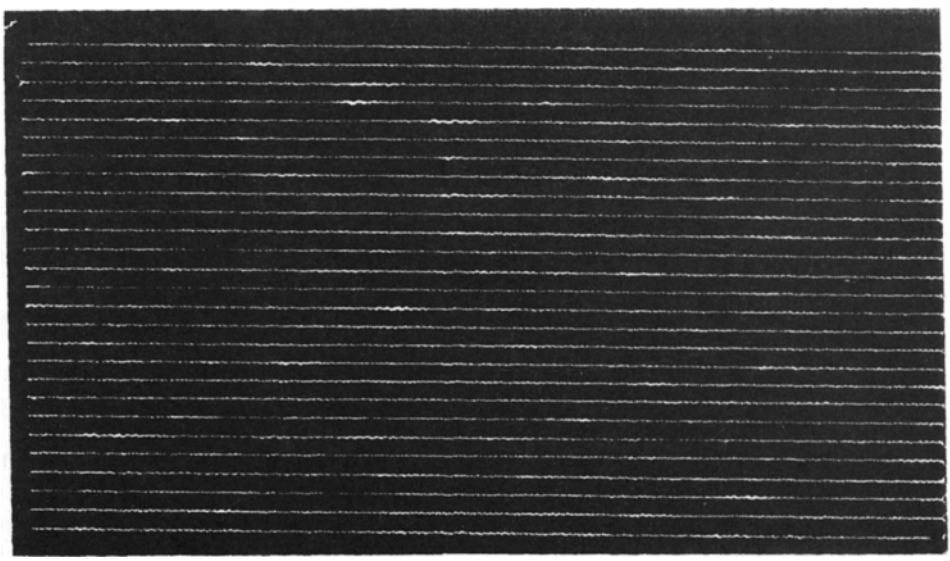


Fig. 2 Appearance of a yarn with improved quality

Table 2 shows the structural information of some of the gimp yarns produced in the research, where yarns with E code were made from rovings. It has been found that the yarns with D and E codes have acceptable quality for weaving, knitting, and braiding, mainly because of the longer effective length of the alginate fibres in the slivers/rovings.

Table 2

Yarn code	Sliver		Filament		Reinforced yarn		
	count (g/m)	eff. length (mm)	core (dtex)	binder (dtex)	count (tex)	K (t/cm.√tex)	alginate (%)
A1	3.7	25.5	94	80	370	34.6	95.3
B1	3.6	35.5	94	80	280	55.2	93.8
B2	3.6	35.5	94	80	230	40.3	92.4
C1	3.1	32.0	94	80	187	47.8	90.7
C2	3.1	32.0	94	80	130	49.0	86.6
D1	2.7	38.5	94	94	172	38.8	89.1
D2	2.7	38.5	167	80	155	38.8	84.1
D3	2.7	38.5	152	80	105	37.6	77.9
D4	2.7	38.5	167	80	70	37.3	64.7
E1	0.7	36.6	154	80	70	35.1	66.6
E2	0.7	36.6	154	80	50	35.4	53.2
E3	0.7	36.6	167	80	50	35.4	50.6

It is evident from Table 2 that while the yarn count is made finer, the alginate content in the gimp yarns is reduced. Together with the twist factor K of the yarn, the absorbency of the reinforced yarns can be controlled for different dressing applications.

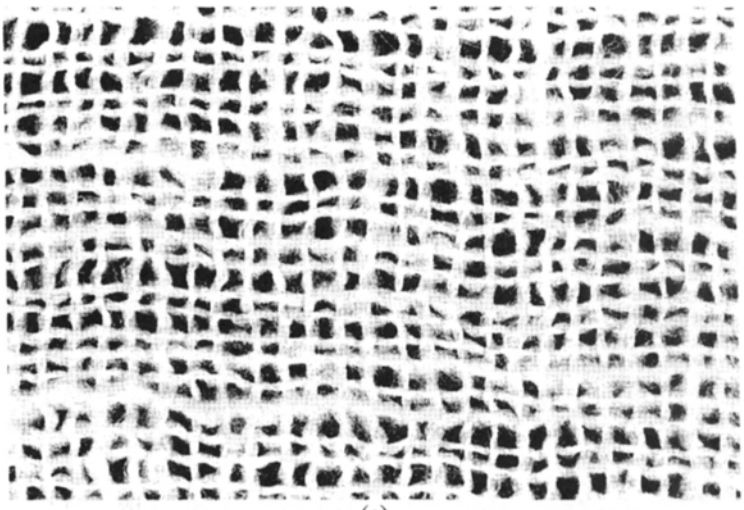
4. The Making of Reinforced Fabrics As Dressings

From the reinforced yarns successfully produced, different types of reinforced fabrics have been generated for wound dressing applications by using weaving, knitting, and braiding technologies.

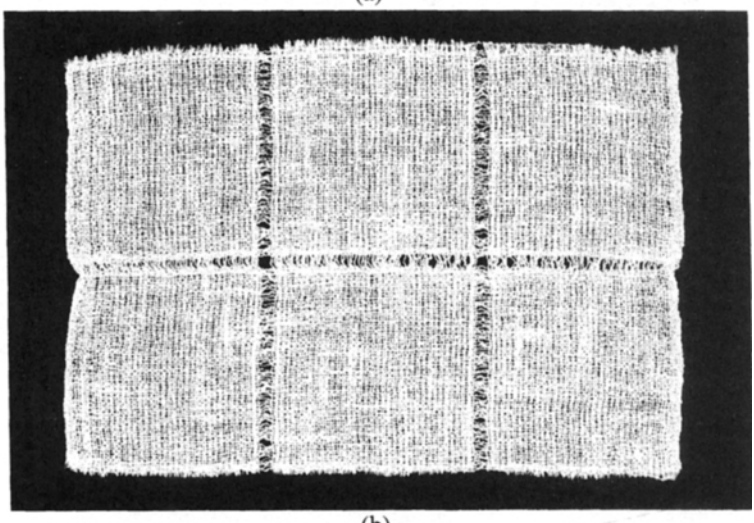
4.1 The development of reinforced woven dressings

Alginate gimp yarns were used in the development of the reinforced woven fabrics as dressings. When such dressings are wetted, the alginate fibres will gel as usual but the filament served as the core and binder will be unaffected and therefore will form a web within the wetted dressing to back the sheet of gel. This will enable the used dressings to be removed easily and integrally.

Woven fabrics were developed for two clinical purposes, namely, for absorbent pads and for contact layers. The contact layers lay between the wound and the other layers of dressing to prevent the wound from sticking to the dressing materials. Thus, contact layer fabrics are required to be able to form a thin sheet of gel without being too absorbent. For absorbency, two types of fabrics were created based on the plain weave, i.e. fabrics with double picks and those with single picks. Yarns with high alginate content were used as warp and weft for these fabrics. For contact layers, all the fabrics are single-pick. While the all contact layer fabrics used alginate yarn for the weft, both alginate yarn and textured polyester filament yarn were used as the warp. Yarns D1 and D2 were used for the absorbent pads, and D3, E1, E2 and E3 were involved in the production of contact layer fabrics. Fig. 3 shows (a) an absorbency fabric and (b) a contact layer fabric.



(a)



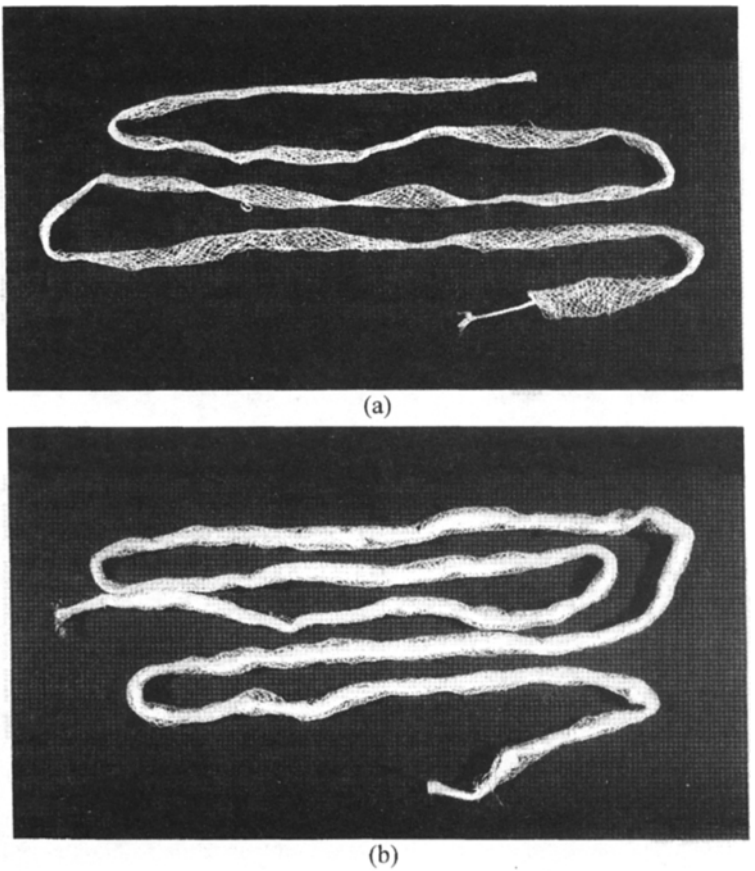
(b)

Fig. 3 (a) An absorbent fabric and (b) a contact layer fabric

4.2 The creation of braided fabrics

Alginate slivers are currently used as dressing materials to treat cavity wounds, and, as already described, the removal of the dressings can be difficult. The creation of the braided alginate fabrics is aimed at improving the dressing performance. Different wounds exude differently, and therefore require dressings with the suitable absorbency. Two types of braided dressings were developed to suit wounds with heavy exudate and with light exudate. The first is a braided tube with required thickness, made from the alginate gimp yarns. Yarns with different alginate contents could be used to control the dressing absorbency. This type is suitable for wounds with light exudate. The second type is a braided tube with an alginate filling, usually an alginate sliver. This structure will allow the

alginate filling to absorb to its maximum capacity, and also will enable the whole dressing to be removed from the wound after use. Fig. 4 exhibits the braided structures.



(a)

(b)

Fig. 4 Braided structures (a) without and (b) with an alginate filling

4.3 The development of knitted fabrics

Trials of making warp- and weft-knitted fabrics from the alginate gimp yarns have been successfully carried out. The weft-knitted fabrics as dressings have the advantage of conforming well around places such as the shoulder, in addition to the dressing integrity after use. The warp-knitted dressings have a stable structure and they are suitable for contact layer applications.

5. Absorbency Tests and Discussion of Results

The reinforced woven and braided fabrics produced were evaluated for performance, using fluid absorbency as the key indicator, dressing integrity being proven not a problem. For the absorbency application, it is expected that the reinforced wound dressing would show absorbency similar to the nonwoven and sliver dressings. In the case of contact layers, a suitably lower absorbency should be sufficient as long as a complete sheet of gel can be

formed. The British Pharmacopoeia method[3] was used for the absorbency tests, the results from which are presented in two ways, i.e., g/g and g/100cm^2. The reinforcing effect in the developed fabrics is so obvious that no test was needed on it.

5.1 Discussion of the woven fabrics absorbency results

Table 3 lists the specification and absorbency of the woven fabrics developed for absorbency application. In the fabric code, AP stands for "absorbency pad", and dp and sp refers to double pick and single pick in the fabrics respectively.

Table 3

Fabric	Yarn count (tex)		Fabric density (1/inch)		Absorbency Na/Ca		Fabric weight & cover	
	warp	weft	warp	weft	g/g	g/100cm^2	g/m^2	%
AP-dp-1	172	172	10	12	7.9	12.2	155	34.5
AP-dp-2	172	172	10	15	7.0	12.4	179	38.8
AP-dp-3	172	172	10	18	6.1	12.7	206	43.1
AP-dp-4	172	172	10	20	6.4	13.3	210	46.0
AP-dp-5	172	172	13	12	7.2	13.2	183	38.4
AP-dp-6	172	172	13	15	6.7	12.8	192	42.7
AP-dp-7	172	172	13	18	5.4	12.6	232	46.7
AP-dp-8	172	172	13	20	5.4	12.5	235	49.4
AP-dp-9	280	280	10	22	3.5	14.0	400	63.3
AP-sp-1	155	155	11	10.5	6.6	9.7	139	32.3
AP-sp-2	155	155	11	11	6.1	9.2	142	33.1
AP-sp-3	155	155	11	12	6.1	9.2	148	34.4
AP-sp-4	155	155	11	13	6.1	9.9	155	35.8
AP-sp-5	155	155	11	14	5.7	8.7	162	37.1
AP-sp-6	155	155	13	14	5.6	8.0	175	39.7

In Table 3, the tightest fabric is AP-dp-9 which was made from a yarn of 280 tex as warp and weft and has a fabric cover of 63.3%. However, the absorbency figures of this fabric are not as high as can be expected in comparison with the nonwoven alginate wound dressings. The absorbency of a normal piece of nonwoven alginate dressing which weighs 100 g/m^2 would typically be 15 g/g and 15 g/100cm^2. This fabric, four times heavier, has only the absorbency of 3.5 g/g and 14.0 g/100cm^2. The absorbency figures of other fabrics show a similar story, i.e. heavier woven fabrics with lower absorbency compared to the nonwoven counterpart. This suggests that in the woven structures, absorbency depends on two aspects, one being the alginate content in the fabric and the other the packing of the alginate fibres in the yarns and the fabrics. If the alginate fibres in the yarns and fabrics are too tightly packed , the potential of the alginate fibres will be restrained and result in a low absorbency.

However, the change in fabric parameters plays a part in influencing the absorbency of the fabrics. It can be seen from Table 3 that increasing the fabric density decreases the g/g absorbency, as the weight increase of the fabrics is faster than the increase of fluid uptake by these fabrics.

5.2 Discussion of the woven contact layer fabrics

Table 4, on the other hand, shows the specification and absorbency of the contact layer fabrics. In the fabric code in this table, CL-all means "contact layer, all alginate yarn" and CL-half suggests "contact layer, half alginate yarn (weft)".

Table 4

Fabric	Yarn count (tex)		Fabric density (1/inch)		Absorbency Na/Ca		Fabric weight & cover	
	warp	weft	warp	weft	g/g	g/100cm^2	g/m^2	%
CL-all-1	105	105	15	14	4.7	7.4	127	35.1
CL-all-2	105	105	15	15	5.0	8.0	132	36.2
CL-all-3	105	105	15	16	4.9	8.0	136	36.8
CL-all-4	105	105	15	17.5	4.6	7.8	142	38.8
CL-all-5	105	105	15	18	5.0	8.2	145	39.4
CL-all-6	70	70	18	16	6.0	-	99	34.0
CL-all-7	70	70	18	17	5.7	-	102	34.9
CL-all-8	70	70	18	18	5.4	-	105	35.8
CL-all-9	70	70	18	19	5.5	-	108	36.6
CL-all-10	70	70	18	20	5.5	-	111	37.5
CL-all-11	70	70	19	17	5.3	-	105	35.8
CL-all-12	70	70	19	18	5.8	-	108	36.6
CL-all-13	70	70	19	19	5.4	-	111	37.5
CL-all-14	70	70	19	20	5.3	-	114	38.4
CL-half-1	18.4	50	32	20	4.8	3.9	79.7	35.3
CL-half-2	18.4	50	32	22	4.3	3.5	80.8	36.8
CL-half-3	18.4	50	32	24	4.1	3.5	84.5	38.1
CL-half-4	18.4	50	32	26	4.1	3.6	88.3	39.6
CL-half-5	18.4	50	32	28	3.9	3.6	90.7	41.6
CL-half-6	18.4	50	32	30	3.8	3.7	97.6	42.6

The relatively low absorbency of the alginate woven fabrics becomes an advantage for the contact layer fabrics. The main function of a contact layer is to form a thin and uniform gel layer to separate the wound and other layers of the dressing pad. The thin alginate gimp yarns were used for the development of the contact layer fabrics. Together with the low linear density of the yarns used, low weight and low cover of the fabrics were achieved by employing suitable fabric densities.

On g/g basis, the contact layer fabrics show a fairly consistent absorbency. In term of g/100cm^2, however, half-alginate fabrics using the 50 tex alginate gimp yarn have about half the absorbency as the all-alginate fabrics from the 105 tex yarn. The gelled half-alginate fabrics forms complete gel sheets and shows acceptable quality for contact layers. Table 4 also indicates that by using different fabric parameters, such as fabric density and yarn count, absorbency can be varied to suit the requirements.

5.3 Absorbency of the braided and knitted fabrics

Braided fabrics were made with and without alginate fillings. While the braided fabrics gel well, the filled braided fabrics show satisfactory absorbency. Table 5 compares the braided fabric with filling to a typical packing dressing product.

Table 5

Dressing	Linear density g/m	Absorbency	
		g/g	g/m
Braided + filling	11	8.5	95
Typical packing	6.7	14	94

The braided fabrics can be made with various parameters. The advantage is that the braided dressing can be removed from cavity wounds completely.

Both weft knitted and warp knitted fabrics were produced for wound dressing applications, too. The weft knitted was intended for absorption and the warp knitted for contact layer purpose. Both showed similar or slightly higher absorbency to their woven counterparts. For example, the warp knitted fabric of 95 g/m^2 shows an absorbency of 5.2 g/g and 5.0 g/100cm^2. This is well suited for the contact layer application.

6. Conclusions

The concept of reinforced alginate wound dressings has been put forward and reinforced yarns, woven fabrics and braided and knitted fabrics for dressings applications have been created with different levels of absorbency. All these dressing fabrics are reinforced and there would be no more removal problems. The absorbency varies according to the alginate fibre content in the dressings and the compactness of the fibres in the yarns and the fabrics. For the same weight, the woven reinforced dressings are less absorbent the their nonwoven counterparts, which makes them more appropriate to be used for wounds with light to moderate discharges. The reinforced fabrics, in particular the woven and warp knitted, are suitable for contact layer applications due to their suitably lower absorbency. The braided fabrics created show good absorbency and they would be effective for cavity wounds as originally intended. The absorbency of all the reinforced fabrics could be easily controlled by specifying the fabric parameters. This, probably, is the other advantage over the nonwoven and sliver dressings apart from the easy removal.

Acknowledgements

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References

1. J.G. Cook, *Handbook of Textile Fibres – Natural Fibres*, MERROW, 1984
2. J.G. Cook, *Handbook of Textile Fibres – Man-made Fibres*, MERROW, 1984
3. Alginate Dressing and Alginate Packing, *British Pharmacopoeia* 1993, Addendum 1995, p1706

4. Opportunities and Challenges for Fibrous Products in Healthcare and Medical Applications

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INTRODUCTION

Significantly large proportion of natural and man-made fibres produced are used as textile fabrics, nonwovens and nonwoven based products in a wide range of healthcare and medical applications. These products include operation room gowns and drapes, wound dressings, bandages, feminine pads, sanitary products, incontinence aids and hospital bedding. Textiles and nonwovens for medical applications are produced according to strict regulations and legistlations. This results not only in the production of safer hospital and biomedical products for the patients but also providing guidelines for the manufacturers of these products. Broadly speaking these products can be classified as 1) hygienic absorbent products, 2) hospital and healthcare products, 3) implants and 4) scaffolds.

In the last decade many important improvements in the quality of commercial absorbent products have taken place. This is due to the new developments in fibre and nonwoven technologies as well as the super absorbent polymers which are incorporated in the absorbent core of these products. The introduction of many novel materials and engineered product design has markedly improved the consumer satisfaction level and increased the market penetration level of these products. Another reason for innovative developments of these products has been the inter-disciplinary efforts in product development involving people from the forest products industry, polymer and resin manufacturers, nonwoven producers and the converting machinery manufacturers.

Because of the large increase in elderly population in many countries it is estimated that the need for adult incontinence products will increase many-fold in the coming decades. There will be increasingly commercial activities aimed at producing good quality products based on innovative materials and novel design options.

Significant progress has also been made in the development of functional nonwovens and textile fabrics for use in operation theatre in hospitals. One of the aims of using OR-textiles is to drastically reduce the occurrence of postoperative wound infection. Also quality of surgical swabs used has improved.

In the area of disposable products, novel nonwoven manufacturing technologies have been developed aimed at combining the functional properties with good aesthetics and comfort. By selecting suitable breathable plastic films the necessary barrier properties against biological fluids and micro-organisms are achieved. Water-jet entanglement process and composite nonwoven structures such as spunbonded-meltblown-spunbonded result in drapable materials which have received a high degree of consumer acceptance.

The textile fabric based OR-gowns and drapes have also undergone major developments as regards yarn quality, weave construction, finishing and launderability. The textile product manufacturers are using the inherent properties of drapability and comfort of textile fabrics as important marketing arguments. Significant improvements have been made as regards treatments for imparting surface hydrophobicity to both woven and nonwoven products.

Textile materials developed for external use on body parts such as bandages, wound-dressings etc are well established products in the medical field. Novel textile fabric structures and the incorporation of elastomeric yarns have resulted in medical products such as compressive bandage where the longitudinal stretch in the bandage material can easily result in the radial forces required for treatment of different body parts. In wound dressings both woven and knitted structures have successfully been used as substrates which are silicone-gel coated for producing suitable mesh structures desired for quick healing of wounds without causing any skin irritation.

For the intra-corporeal use of textiles such as implants there are already many successful applications. These include their use in ligaments, vascular grafts and prostheses. For biomedical applications where biostability is required, non-resorbable polymers such as polytetrafluoroethylene, poyurethanes, polyester are used. In addition to imparting the physical and mechanical characteristics such as stiffness and strength as a supporting material when used as ligaments and prosthesis, these materials must be biocompatible with the tissues of internal body parts. Many research teams world-wide are studying various means to improve biocompatability of textile fibres made of different polymers.

The suture threads made of resorbable polymers such as polylactides or polyglycolide are now common. With mechanical properties similar to those of certain thermoplastics, PLA and its copolymers are also biocompatible which makes them suitable for use in medical applications. These polymers are degraded in the body by hydrolytic or enzymatic cleavage of polymer chains and the residues taken up by the body without causing any harmful effects on humans.

At this year's TECHTEXTIL Symposium in Frankfurt, a unique one-day presentation was made by some German textile and medical research institutes on the topic "Textile Biomaterials – New Possibilities for Medical Applications". Those papers covered most of the issues relevant to this presentation [1].

OPPORTUNITIES AND CHALLENGES

Tissue engineering

It is expected that by the year 2010, a number of human organs and body parts ranging from skin, bones, heart and pancreas can be artificially produced by using very innovative techniques. Already human skin, several meters in length, have been successfully produced in research laboratories. Within the framework of a large international project called LIFE, some 13 top scientific teams from many countries are working in the field of tissue engineering i.e., the work aiming at engineering and producing living biological material. The vision of these scientists is to produce in not so distant future human tissue from all human organs [2, 3].

The basic principals underlying this research work is that living cells are removed from human organs which are then cultures on a tissue culture in the laboratory. By supplying the correct nutrition to the cells and by incorporating suitable natural proteins as growth factor, one can make the cells to divide and grow. In order to guarantee that the correct shape of the new human organ is achieved, the cells must be allowed to culture and grow on a scaffold made of biologically degradable polymeric material. According to experts it should be possible to grow cells on various parts of a human organ on a suitable scaffold followed by biologically joining the parts together to form the final shape.

Specialists from various scientific and medical fields are in the process of developing methods to proliferate cells into tissues and body parts such as skin, connective tissues, bones and blood vessels. At present these experiments are being carried out in the laboratories and many clinical trials have been made. Experts predict that a battery of human organs as human reserve parts will be available within a decade. The above developments present great high-tech opportunities and challenges for the fibre, textiles and nonwoven industries because the organs will have to be developed on fibrous substrates of varying geometrical form and shape. The polymers of which the fibres are made have to be biocompatable and resorbable types. The scaffolds preferably should have certain desired characteristics. For example they shall have large specific surface area, have three dimensional structure and degrade with time. The desired characteristics can only be offered by textile and nonwoven structures, for example, made of micro-fibres spun from biodegradable polymers such as PLA and PGA.

Polymeric materials for biomedical application

Although the science and technology of polymers in biomedical applications is at an early stage of development, they are already used as permanent implants, in contact lenses, suture threads etc. A biomedical polymer should possess appropriate mechanical and physical properties. It should have good tissue, cell and /or blood compatibility. The properties related to ageing in the body should be taken into consideration. The polymers must possess resistance to sterilisation and have sufficient shelf stability.

The use of artificial prosthesis such as artificial tendons, ligaments, vascular prosthesis is becoming more widespread. Synthetic polymers such as polyester when used in fibre form provide great opportunities to form the basic material for artificial prosthesis. By using the latest manufacturing technologies for producing different types of textile structures, it should be possible to use CAD-techniques to design the most suitable structures for different applications. These products can be engineered using the appropriate techniques for achieving the required shape, flexibility, surface topography and surface chemistry for a given end-use [4].

The primary focus in the search for materials in biomedical applications is to find a biocompatible material. The meaning of the term biocompatibilty includes a wide range of definitions. A material may be biocompatable in one application but not in another. A successful use of a material as medical device requires both acceptable biological response to the material and the absence of physiologically induced damage. The performance of the material in its biological surroundings is a measure of the overall interaction between the surface of the material and the living system. The biological response to the synthetic material is governed by the nature of the outermost layer of the surface. The surface of any polymer material within a biological system will induce rapid and complex series of biological events. However if the artificial material in its physical properties resemble the living tissue it will replace, and in addition, the surface is biologically active the material should have a good chance of being accepted by the biological system.

Polymers with biologically active surfaces

The non-resorbable polymers in medical use of today include polyethylene, polypropylene, polyvinylchloride, polyester, polytetraflouroethylene, polyurethane, polyacrylnitrile, silicone rubber and polyacrylates. Many of these polymers are not considered to have biologically active surfaces. To be able to immobilise catalysts or

enzymes on the surface of for instance polypropylene the surface has to be altered to introduce reactive sites for further reactions. A diverse range of surface modification procedures and techniques have been studied including plasma modification and polymerisation. If polyacrylnitrile is used as a matrix for biologically active species the polymer itself can provide nitrile-groups that can be used for further reactions.

Another approach for developing polymers with biologically active surfaces is to produce hydrogels. Hydrogels resemble in their physical properties living soft tissue more than any other class of synthetic biomaterials. These highly hydrated polymer networks are usually mechanically weak. However there are a number of approaches which can be taken to minimise problems due to the poor mechanical properties of these gels.

Surface treatments of polymers for improving biocompatibility.

The surface of fibres and polymers used in biomedical applications can be made biocompatible by attaching functional groups to the polymer surface. Plasma treatment by itself and plasma grafting using monomers, have shown to increase the hydrophilic behaviour of polymers and enhanced cell growth. Imparting functional groups on fibre surfaces provides an effective base for further chemical reactions with biologically active molecules, e.g., special proteins like enzymes and growth factors, or even antibodies. These molecules can covalently be immobilised through OH-,NH_2-, COOH-functions. It has been stated that such a finish also favours the growth of adherent cells. The plasma induced graft polymerisation of functional hydrophilic monomers on the polymer surfaces has been shown as an approach for introducing functional groups suitable for covalent immobilisation of bioactive molecules like cell adhesion mediators (fibronectin) [5].

Fibre-reinforced composites for surgical implants.

Many publications are found in the literature dealing with various aspects of fibre reinforced polymer composites for surgical implants [6, 7]. Some of the property requirements of the implants are load-bearing capacity, corrosion resistance, low weight, very low allergic risk, x-ray transparency, durability, easier handling and biocompatibility.

The textile industry has now access to fibres and yarns with high tensile strength, modulus and resistance to hydrolysis. Some of these methods can be used both as fibre reinforcement and in a modified form as matrix materials in forming of fibres or films. Production of pre-pegs made from reinforcing fibres and thermoplastic matrix fibres offer great opportunities to design pre-pegs for producing surgical implants. There are a number of advantages of textile techniques using the thermoplastic matrices over other types of techniques using thermoset matrices RTM, for making composites. These include homogenity of matrix and reinforcing fibres, high drapability and solvent process.

Having access to high performance fibres with high stiffness and strength and by the selection of appropriate fabric structure giving the necessary formability, it is now possible to design many types of implants. Many new types of high performance polymers can be tailor-made both as the reinforcement yarn and in modified form as the matrix in the textile composites. Furthermore recent advances in technologies to produce 3-D shaped fabrics from woven, knitted and braided processes would also make it easier to design the surgical implants where the mechanical and physical

requirements are easily fulfilled. The biocompatibilty of these products, however, is still the most important factor for their acceptance as functional implants.

CONCLUDING REMARKS

The driving technological force in new application for fibres thus far has been material development spear-headed by the advances made fibres, polymers and chemical technology.

In the fibre technology area relevant to medical applications, there has to be greater use of high functional and high performance fibres as well as development of new industrially viable surface modification techniques such as plasma treatment for producing functional fibres and fibrous products. The characteristic low surface energy of many polymeric substrates results in intrinsically poor wettability and adhesion. The use of biopolymers as source of producing synthetic fibres has to be fully exploited.

The technical textile industry is in the midst of a phase full of opportunities. The advances in materials and technologies and our understanding of various requirements for fibrous products in medical application should lead to products with sought-after characteristics in the areas of hygiene and hospital products as well as extra-corporeal and intra-corporeal medical devices. For example, nonwoven resorbable polymer structures produced by melt-blown technology offers excellent possibilities as scaffolds for tissue engineering whereas 3-D braiding technology could offer interesting solutions for producing surgical implants. In any case the future solutions require close co-operation between the textile scientists and the medical experts.

Many of the medical applications of fibrous materials demand a sterile product. It is of vital importance that the materials based in biomedical applications can withstand the conditions of sterilisation depending on the type of treatment such as steam, dry heat, ethylene oxide gas and irradiation.

At present we are seeing the beginning of a new era where fibre based materials are finding opportunities of exciting applications for biomedical end-uses. The important R&D needs are summarised in Fig. 1.

REFERENCES

1 "Textile Biomaterials", Block 6.1 and 6.2, Proceedings *TECHTEXTIL Symposium 1999*, Frankfurt, Germany, 1999.

2 "New Organs grow in the laboratory", "Illustrerad Vetenskap" No. 5 1999, 10-19, (in Swedish).

3 A. Arnold, M. Dauner, M. Doser and H. Planck, "Application of 3-Dimensional Structures for Tissue Engineering", Lecture No. 618, Block 6.1 Proceedings *TECHTEXTIL Symposium 1999*, Frankfurt, Germany, 1999.

4 M. Dauner and H. Planck "Composite Biomedical Materials for Surgical Implants", Textile Asia, Feb. 1999, 33-37

5 C. Oehr, M. Müller and U. Vohrer, "Surface Treatment of Polymers Improving the Biocompability", Lecture No 615, Block 6.1, Proceedings *TECHTEXTIL Symposium 1999*, Frankfurt, Germany, 1999.

6 P. Christel, L. Claes and S.A. Brown, "Carbon-Reinforced Composites in Orthopaedic Surgeing in High Performance Biomaterials". Ed. Michael Szycher, Technomic Publishing Co. Inc., Lancaster, 1991, 499-518.

7 C. Linti, M. Dauner, M. Milwich and H. Planck, "Fibre Reinforced Polymers for Implantation", Lecture No. 617, Block 6.1, Proceedings *TECHTEXTIL Symposium 1999*, Frankfurt, Germany, 1999.

Figure 1: Sophisticated Fibrous Structures for Medical Applications.

DEVELOPMENTS NEEDED

Polymers & fibres

- Resorbable polymers
- Suitable fibre extrusion systems
- Micro-fibres
- Complex fibre cross-sections
- Hollow fibres
- Antibacterial fibres
- Slow-release fibres

Fibrous structures

Scaffolds

- Novel nonwovens, woven and knitted techniques for producing substrates containing large specific area, high porosity, formability and handleability.

Fabrics

- High functional and high performance structures
- Novel weaving, knitting, braiding technologies for producing artificial vascular prosthesis, ligaments etc.

Surface Treatments

- Enhancing biocompatibility
- Functional surfaces

Surgical Implants

- Thermoplastic composites using textile pre-pegs

Surgical Swabs

- High absorption, non-linting

Anti-decubitus Material

- Reducing pressure-sores and bed-sores

5. Knitting Seamless Three-Dimensional Shell Structures on Modern Electronic Flat Bed Knitting Machines

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INTRODUCTION

Textile structures have been used for medical applications for many years. However the importance of textile structures in medical applications has increased over the last few decades. Textile structures are currently produced by binding yarns or consolidating fibre webs. All the above described textile structures are considered two-dimensional (2D) structures as the fabric thickness can be neglected when compared to the fabric length and width. In the clothing industry these 2D textile structures are formed into a 3D garment using extremely labour intensive cutting & sewing techniques. This method, however, is not the most suitable way of producing 3D structures for medical applications, either due to economical reasons or seams. The modern flat-bed knitting technology provides a pathway towards producing 3D seamless structures in one piece.

CLASSIFICATION OF 3D KNITTED STRUCTURES

The 3D textile structures that can be produced are classified into the following two groups:

- 3D shell structures;
- Solid 3D structures.

Knitting 3D shells

A fabric tube knitted on a circular knitting machine can be described as the simplest 3D shell structure that can be manufactured. This technology has been improved and perfected today to manufacture jerseywear, complete socks and other hosiery products. During the last two decades a technological revolution has taken place in flat-bed knitting machines. In order to knit 3D shells on a flat-bed knitting machine a high degree of precision on the needle movement, control on the individual knitted loops (loops on the needle hooks) and yarn delivery is vital. Due to the integration of electronic needle selection and mechatronic systems the modern electronic flat-bed knitting machine meets the majority of the above requirements. The important features of a modern electronic flat-bed knitting machine are given below:

Needle and cam selection: electronic individual needle selection, knitted loop transfer 3-way technique

Knitted loop control: integration of holding-down sinkers on to the needle-beds, use of motors to drive the take-down rollers in very fine steps, fast drive and reversing of the take-down rollers

Stitch length adjustment: positioning of lowering cams using stepper motors, this facilitates the variation of the stitch length during knitting

Carriage drive: use of frequency controlled ac motor with electronic reversing clutch, automatic adjustment of the carriage stroke according to the knitting width

The technology of knitting 3D shells on flat-bed knitting machines is based on:

1. Begin forming stitches on empty needles;
2. Transfer knitted loops on selected needles to neighbouring needles and discontinue forming stitches on the needles selected;
3. Holding on to knitted loops on selected needles while forming stitches with the others;
4. Stitch length variation;
5. Varying the inclination of groups of wales in a rib knitted structure by integrating tuck loops with racking sequences.

The full potential of this new technology is still not fully exploited in creating novel and more value added 3D medical appliances. There are many methods for creating 3D shell structures on a flat-bed knitting machine. Two methods are described below.

Method 1

A 3D shell structure can be knitted by opening out the 3D shape into a 2D shape. During the knitting of the opened out 2D shape its selvedges are connected in order to create the required 3D shell structure. This technique is explained using the example of knitting a top-open box. Opening out the 3D shape will produce a knitted panel of the shape given figure 1b. In order to form a 3-dimensional top-open box this panel must be folded along the lines AB, BG, GH and HA and the edges need to be seamed as demonstrated in figure 2.

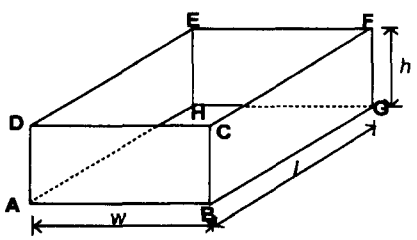

Fig :1a: 3-dimensional shape of top-open box

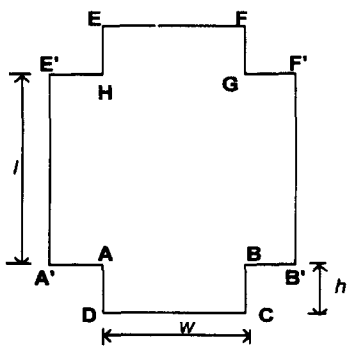

Fig 1b: 2-dimensional planar shape of the opened out box

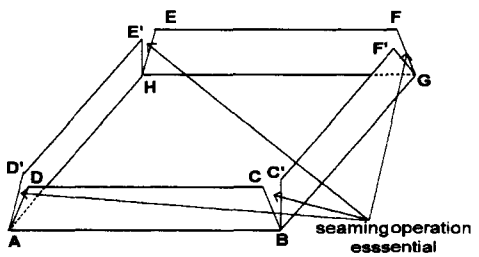

Fig 2: Top open box

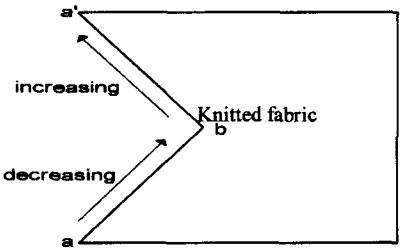

Fig 3: Creating a 3D seam on a flat-bed knitting machine

In order to knit a 3-dimensionally formed top-open box the four seams need to be formed on the flat-bed knitting machine.On a flat-bed knitting machine a 3D seam can be formed by using the technique of holding on to knitted loops on selected needles while forming stitches with the rest. This involves putting predetermined needles temporally out of action and later bringing these back into operation. In this method the knitted loops are held in the hooks of the needles, that are left inactive while other needles continue to knit.

The decreasing operation (de-activating needles) will form line 'ab' and the increasing operation (re-activating needles) the line 'bá'. During the decreasing and increasing operations the inactive needles hold on to the knitted loops in their hooks. As a result the selvedge lines 'ab' and 'bá' will form a seamless edge. This seamless edge will also force the knitted panel into the third dimension. When applying this technique to create seams and/or 3-dimensional shapes the knitting process must be carried out with a minimum take-down tension. The very first needles taken out of action hold the knitted loops over several courses until required shape is achieved. If the take-down tension rollers are employed the take down-tension will not be constant across the width of the panel.

To apply the above method to knit a top-open box, the opened out pattern given in figure 1b has to be modified as given in figures 4b.

In the figure 4a edges AB, DC EH and FG are not true edges. The top-open box is formed with edges BI, HJ, GL and CK. In order to prevent puckering at the edges, deactivating and reactivating of the needles should be carried out over equal number of courses. This would result in a widening and narrowing angle of 45 degrees at the edges BI, CK, HJ and GL. The knitting process is described below in detail.

Start knitting from the edge IK. Needles at the selvedges are gradually put out of action until points B and C are reached with the knitted loops held in the hooks of the respective deactivated needles. Once the points B and C are reached the deactivated needles are gradually brought back into action until points I' and K' are reached. This would create the seamless edges BI and CK.

Method 2

Another rather interesting technique for creating 3D shell structures is based on integrating tuck loops with racking sequences with a rib structure. The orientation of the wales is altered by racking a needle bed during knitting. By organising this wale inclination into groups 3D shell structures can be created.

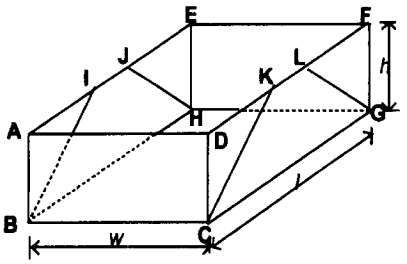

Fig 4a: 3D shape of a top-open box

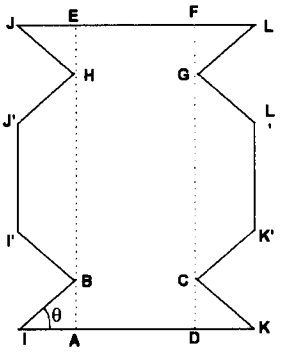

Fig 4b: Modified 2D planar shape

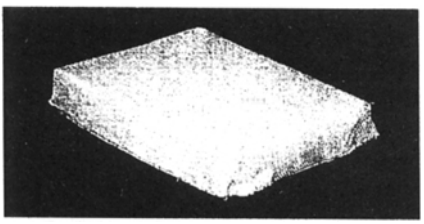

Fig 4c: Knitted top-open box

The 3D shape is formed during the relaxation of the knitted fabric.

Knitting 3D solid structures

Sandwich structures

Currently, only solid structures of limited thickness can be formed via the knitting route. These structures are created by knitting two individual fabric layers on two needle systems and connecting these using a filling yarn. The structures are known as sandwich or spacer structures and they can be knitted on flat-bed knitting machines.

Yarn Feeding on V-Bed Knitting Machines

Despite the progress made by flat-bed knitting machine builders in controlling the knitted loops (fabric take-down) and needles, these machines have inherent problems associated with feeding the correct amount of yarn to the needles at low tension. In many respects this problem has been resolved on modern high-speed circular machines through the provision of effective positive feed systems. The Knitting Research Group at UMIST dedicated the last seven years of work to developing feeding solutions for modern flat-bed knitting machines. A weakness of the majority of modern flat-bed knitting machines is the need to accommodate the feeding of yarn to a reciprocating knitting system. The yarns are guided to the yarn carriers from the sides of the machine (needle beds), so that the yarn path is straight and avoids interference from moving parts. One or more spring loaded cymble tensioners are integrated into the yarn path to maintain the yarn under tension, and a return spring is fixed next to the yarn package to

draw back any excess yarn in the initial stages of the carriage movement towards the yarn guiding side of the machine. Theoretically in weft knitting the needles should have only **one** function, i.e. to form stitches, but, unfortunately, in order to carry out the above function the knitting needles also must pull the required length of yarn from the yarn package. The result is that the run-in yarn tension will be much higher than the yarn unwinding tension at the package, because the yarn has to overcome all the frictional drag along its path.

For a run-in-yarn tension of 3.0 cN the yarn tension at the take-back spring can be calculated by applying the Euler's capstan equation. The yarn tension components for a yarn with an average coefficient of friction of 0.16 are given in the table 1. Thus the disc tensioner (11) should be set to a value which is slightly higher than 8.20 cN in order to take back the yarn and maintain it straight. In this way the correct setting of the cymbal yarn tensioner will cause the tension in the yarn length between the guides (5)

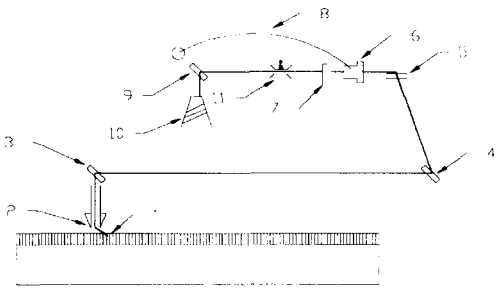

Fig 5:Yarn path on a flat-bed knitting machine

Position	Yarn Tension in cN
Just before the needles	3.00
Between 2 and 3	3.86
Between 3 and 4	4.96
Between 4 and 5	6.38
Between 5 and 6	8.20

Table 1: Theoretical yarn tension components along the yarn path.

Position	Yarn Tension in cN
Between 6 and 5	9.00
Between 5 and 4	11.57
Between 4 and 3	14.88
Between 3 and 2	19.13
Just before the needles	24.59

Table 2: Theoretical yarn tension components along the yarn path after adjusting the cymbal yarn tensioner.

and (6) to increase. By assuming the tension between (5) and (6) to be 9.00 cN the run-in yarn tension values can be calculated, and these are given in Table 2.
This example shows that on flat-bed knitting machines the run-in-yarn tension can very easily build up to higher values and this can cause particular problems with weaker yarns and yarns with low extensibility.
Another undesired effect is the yarn tension peaks which occur when the carriage is returning towards the yarn guiding side of the machine and this is caused by the inertia of the take-back spring and its bending stiffness.
A further feeding problem is caused by the reciprocation of the carriage. This causes the run-in-yarn tension to vary during the knitting of alternating courses due to the unwinding of unequal lengths of yarn from the yarn package depending on the direction of the carriage movement. When the carriage travels away from the yarn feed-side, the course length plus an additional length corresponding to the distance travelled by the yarn carrier will be drawn off from the yarn package. When the carriage travels in the opposite direction the length of yarn drawn off would equal the knitted yarn length minus the distance travelled by the yarn carrier. Another complicating factor which has to be taken in to account is the yarn velocity. At the beginning of a new course the carriage together with the yarn carrier accelerates from zero velocity until it reaches its nominal knitting velocity, and at the opposite end of the needle bed, i.e. shortly before the end of that course, it is decelerated and brought to rest. This results in a discontinuous yarn movement. It is inevitable with such a system that the ballooning tension will differ between one carriage direction and the other and in the absence of a positive feed system this will lead to differences in yarn delivery tension at the needles and consequent differences in stitch length.
All these features of a reciprocating knitting system contribute to the difficulty of providing equal yarn lengths to each course and to each needle and these difficulties are compounded when weak and stretch sensitive yarns are knitted.

NEW YARN DELIVERY SYSTEMS DEVELOPED AT UMIST

Yarn accumulator

The resultant yarn velocity due to reciprocation of the yarn feeders leads to variation in yarn feed velocity. This is given by

$$v_R = v_N + v_C \qquad (1)$$

where

v_R = the resultant yarn velocity
v_N = the rate of yarn demand to form stitches by the needles
v_C = the velocity of the yarn carrier.

On flat-bed knitting machines the yarn velocity is fluctuating. It is known that the tension in a moving yarn is influenced by its speed. In fact on flat-bed knitting machines higher run-in yarn tension values have been measured with increasing carriage velocity. Theoretically, the yarn velocity fluctuations can be minimised by eliminating the yarn carrier velocity component (v_C), so that

$$v_R = v_N \qquad (2)$$

If this could be achieved it would result in a situation similar to that in circular knitting. The above objective can be achieved by integrating a yarn accumulator (storage feeding device) directly into the yarn carrier.

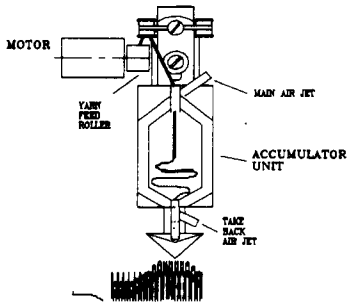

Fig. 6: Schematic diagram of the yarn accumulator

Such an arrangement would not only eliminate yarn tension fluctuations caused by yarn velocity fluctuations, but also allow the yarn to be supplied to the knitting needles with a near zero tension. The major component of the research at UMIST involved the development of the means of storing yarn directly on the yarn carrier with help of an accumulator. The shape and the size of this accumulator was determined by the dimensions of yarn carrier, and due to the yarn carrier's limited size the yarn had to be stored in the accumulator in a compacted form, so it was continuously available during the stitch formation process.

A problem, which had to be solved was to devise a method of packing yarn without entanglement due to the untwisting of yarn. The accumulator was designed to prevent the yarn from twisting into a third and undesirable dimension. It was also designed to prevent stretching and deformation of yarn by the accumulator.

In the first prototype a motor driven yarn feed roller was employed to draw the yarn from the package and it was then blown into the yarn accumulator by compressed air of 2 bar pressure. This accumulator could store up to 1.5 meter length of yarn depending on the yarn count. This length of yarn acted as a storage buffer allowing yarn to be drawn out with a very low tension. The accumulator chamber was constructed with two pieces of perspex separated by 1.5 mm height pillar border which formed a thin gap cavity. Yarn was blown into the yarn accumulator with a nozzle and compressed air. This design caused the yarn to be stored in layers inside the accumulator due to the air flow inside it. The schematic diagram of the first prototype accumulator is shown in figure 5. In order to test the feasibility of knitting the prototype was fitted to a yarn carrier of a Stoll 14 npi flat-bed knitting machine. A PC was used to control the yarn feed roller motor and the air jet. All the connection wires and air hoses were placed inside a chain link trunk which allowed a flexible suspension of these to avoid disturbing the yarn path.

The first prototype showed that the prerequisite for the efficient operation of the new concept was to have a minimum length of yarn available in the accumulator at all times. Based on the experience gathered with the first prototype a second prototype was designed. In the new design it was decided to move the feed roller and the motor away from the yarn carrier to the side of the needle bed. The motor speed had to be in accordance with the yarn demand, and this required an efficient microprocessor based feedback control loop for the operation of the motor. Prior to the beginning of knitting a new course the yarn accumulator was filled up to a pre-set level due to the action of the motor and the air jet and during knitting this pre-set yarn level was maintained by the microprocessor based feed-back control system. Knitting trials have shown this novel system to be effective in eliminating the tension fluctuations due to reciprocation and preventing many of the faults which are caused by excessive tensions within the

knitting zone. It therefor offers the potential to facilitate the knitting of difficult yarns such as alginates. However it does not provide true positive feed as yarn is supplied on demand and further research at UMIST has had as its objective the development of a true positive feed for v-bed machines.

True Positive-yarn delivery for Flat-Bed Machines

The prerequisite for controlling the dimension stability of a knitted structure is to control the stitch length, which in our opinion will be possible with a true positive yarn feeding system. When knitting jacquard structures one needs to control only the yarn which knits the ground structure or colour. A second project was launched, therefore, to create a true positive yarn feeding system to control the size of the stitches formed with the ground yarn. The basic concept of the positive yarn feeding system was to release a predetermined length of yarn to the knitting needles to form stitches. The length of the yarn to be released to the needles can be calculated from the knit pattern. The new yarn feeding device was mounted on to a Dubied Jet 3F machine. Software was created to drive the servo motor directly from the PC according to a programmable stitch length, and carriage position. Some results of the knitting trials are given in figures 7a and 7b.

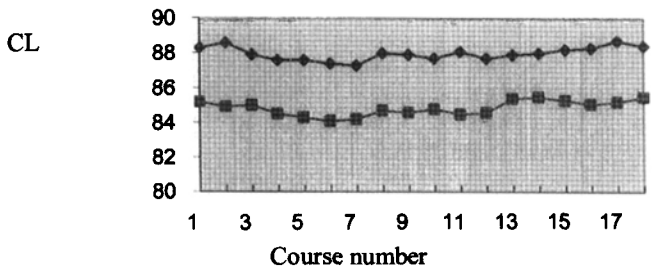

Fig 7a : Course lengths when knitted without positive feeding

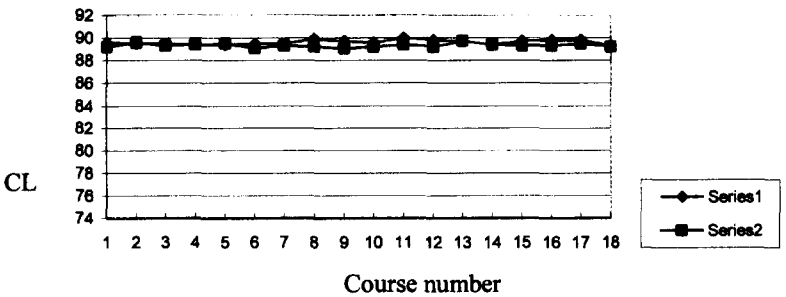

Fig 7b : Course lengths when knitted with UMIST positive feed system

Our solution to control the stitch length on flat-bed knitting machines is to knit the ground yarn by using a true positive yarn feeding system and to knit other required yarns with a accumulator feed system. The yarn accumulator would allow tension sensitive yarns to be knitted at higher speeds, and at the same time products of correct dimensions can be knitted due to the true positive yarn feeding system controlling the ground yarn.

6. Medical Textiles with Specific Characteristics Produced on Flat Knitting Machines

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INTRODUCTION

Flat bed or V - bed knitting technology goes back to the invention of the American Isaac W. Lamb in 1863. His idea to use a forward and backward moving carriage with integrated systems to control the function of needles, positioned in two needle beds, still represents the center piece of any modern flat knitting machine. Since their first industrial use these machines have always been producing fabrics for the knitwear industry, such as for sweaters, vests, scarves, caps etc. Technical or non fashion related applications have been of less importance. However there is a growing interest in the technology, since the specific qualities of fabrics knitted on such machines as well as the exceptional way of production have been recognised for new technical, particularly medical applications.

PARTICULARITIES OF FLAT KNITTING TECHNOLOGY

Even if the working concept of these machines still corresponds to the original idea of Mr. Lamb, the development has gone ahead and led to machines with production capabilities as requested by modern industries.
At the beginning of 1920's the development went over from the original Links/Links technology - where needles with one hook at each end were shifted between two horizontally positioned needle beds - to the typical and still valid V – arrangement of the needle beds. Furthermore originally mechanically driven Jacquard motions were replaced by modern, electronically controlled single needle selection systems with three way knitting and transfer operations. Thus needles on a modern flat knitting machine knit, tuck, miss, split and transfer stitches.
The function control of the knitting systems, as well as the cam position determining the stitch length is set by step motors, which are able to adjust their positions during a course and therefore allow an individual control of the needles.
The production of 3 dimensionally shaped fabrics is supported by positively controlled sinkers on both needle beds, which press down the last row of stitches during the formation of new stitches or other knitting operations.
The product development of knit articles, including the design for Jacquard and shape as well as program and machine parameters is nowadays performed by means of a very powerful pattern preparation unit, which encompasses the tools for product implementation and production control. Stoll offers a set up which allows an online connection between the CAD unit (Sirix 110) and the machines. In addition an internet hook up is feasible as well. Thus a complete CAD/CAM operation can be installed.

The V – bed arrangement allows the production of various forms of knitted fabrics:

- single layer fabrics (=> jersey)
- tubular fabrics with varying diameters even within one piece
- spacer fabrics (=> tubular fabric construction with tuck stitch connections)

- all needle knits (Rechts/Rechts)
- weft inserted fabrics

All fabric types can be combined by applying them horizontally or vertically within one fabric piece.

The combination of stitch transfer and racking operations are used for narrowing fabrics. Just by adding stitches on the selvages, the fabric can be enlarged. These are the basic methods, which are applied to knit a fabric to shape. The so called fully fashion sweaters are sewn together out of body parts and sleeves, which are knitted to shape.
Under the pressure of textile imports out of low cost – countries, the demand rose for a knitting machine, which is able to produce completely assembled sweaters. With the introduction of the CMS 340 knit and wear machine in 1997 Stoll reacted to this demand and nowadays offer a machine, which joints three simultaneously knitted tubes to a complete sweater by means of stitch transfer and linking operations. The ability to create these sweaters makes this procedure a very attractive and competitive way to produce jumpers even in high cost – countries as many labour intensive production steps like cut and sew operations become obsolete. Beside missing finishing processes additional production related advantages make the flat knitting technology a manufacturing procedure which has gained importance not only for fabricating knitwear but also for producing knitted technical textiles as well as medical textiles.
The described possibility of producing knitted to shape articles gets even larger by applying the so called wedge technique. Hereby subsequent stitch courses are narrowed regularly up to a certain point, where the stitch courses begin to extend again - needle by needle up to the original wale. The needles, which are temporarily out of operation, have not cast off their loops. When they start forming loops again, they connect the last with the new stitch. Thus an original two dimensional fabric can be bent to a three dimensional form (similar to the reversed process of peeling an orange). This process can be continued and adapted up to a round shaped body. The formation of individually shaped two and three dimensional objects even gets more useful by the incorporation of additional elements such as pockets and tubes for fixation purposes and the insertion of parts as well as of specifically placed openings, which normally have to be cut in. The so called Intarsia technique allows for such openings without the necessity to hem the edges in a subsequent step.

The benefits which are performed by the knit-to-shape procedure get improved by considering, that there are no preparation processes needed like warp preparation and sizing. The flat knitting machine processes yarn directly from cones, which consist of yarn, that is either package-, spun- or solution-dyed. Thus, there is no additional dying process necessary. This makes flat knitting extremely flexible and helps to cut costs not only by reducing processing steps but also with regard to optimised material consumption and waste reduction.

Besides cost effectiveness the flexibility offered to production planning and pattern creation is another big issue, which has increased the acknowledgement of this technology. The aforementioned ability to design knitted textile products out of different fabric formations in combination with varying qualities and material compositions has made flat knitting a technology which is more and more looked at for the production of modern and innovative textile applications. The most important factors are for:

- elasticity control => floats or weft insertion of low elastic material
- compression effects => floats or weft insertion of highly elastic material
- open mesh structures => needle selection and transfer structures
- specific + restricted material applications => Intarsia technique
- combined processing of yarns with different characteristics => plating
- padding and moulding effects => spacer applications and structural stitch allocations

These basic construction methods are also used for medical textiles with varying characteristics. The following documentation of the various application possibilities show areas where textiles produced on flat knitting machines already represent a standard but also fields where the technology has just begun to be tested for its performance. They are explained here to show the versatility of this production procedure but also to explore new fields of applications in the world of medical textiles.

KNITTED TO SHAPE ELASTIC TEXTILES FOR PHLEBOLOGICAL, HYPERTROPHIC AND ORTHOPAEDIC USE

Compression stockings

In western countries venous diseases, particularly in the calf area, are very common. About half of the adult population consult their doctors about problems with their leg veins at some stage during their lives. 10% to 20% of the population suffer from varicose veins and it is about twice as common in woman as in men.

Varicose veins arise because of an inherited tendency as well as of environmental factors. A western way of life is more likely to result in varicosities than living in a developing country. The symptoms caused by incompetent veins (=> failure of flap valves) are variable and might start with small varicosities (dermal flares), which go on passing phases of stronger appearance up to chronic venous insufficiency (CVI) with final ulceration. Presumably 20% to 50% of all cases of venous ulceration are originally caused by varicose veins.
Depending on the actual state of the venous insufficiency there are different surgical possibilities for relieve. One method which is generally applied either as a treament of the symptoms for varicose veins as well as for the prevention of venous ulcers is the wearing of compression stockings. Medical compression stockings apply external pressure to the leg with the effect to increase the blood flow velocity and to counteract raised venous pressure.
Depending on the various needs of the patients there exist different types and classes of stockings. In most of Europe stockings are divided into four classes of compression with class # 1 applying the lowest and class # 4 the highest rate of compression. In all classes the pressure rate decreases from the ankle area with 100% to about 70% around the knee and finally 40% in the thigh. Pressure stockings are available as calf-length socks, thigh socks and tights.

Compression stockings are nowadays produced on circular knitting machines and on flat knitting machines. The quality which is made on circular knitting machines mostly covers classes 1 to 3, whereas the stockings produced on a flat knitting machine reach from class # 2 up to class # 4. Their characteristics are, that:

- they are knitted to anatomical shapes
- stockings of class # 3 and # 4 are individually made to the patient's leg measurements
- they incorporate a very strong elastic yarn (double twisted) as an inserted weft, which guarantees very high compression values
- they represent relatively heavy qualities. The standard for this type of stocking is knitted on machine of gauge E 14.

The manufacturing of elastic stockings

The perfect fit is a must for such a type of stocking to make sure, that the right compression is provided. The measurements are taken by the doctor and made available to the stocking manufacturer. They use their own calculation programs to determine the correct fitting of the stocking by considering an adapted size for generating the pressure which has to be achieved. The calculated forms are used by the pattern preparation system (Stoll - SIRIX 110) and converted into a Jacquard and command program which can be interpreted by the machine control.

If the set up is existing in the production plant, the Jacquard and machine parameters can be transmitted automatically to the flat knitting machine via an online connection between the knitting machine and the pattern preparation system. The Stoll software allows an active communication between the machine and the SIRIX design system and thus enables an automatic production control. Such a procedure is important for the manufacturing of custom - made stockings as the organisation of the production represents the processing of a series of single orders.

The processing of elastan fibres demands special machine equipment to ensure a constant and even compression effect. Stoll developed a particular yarn feeding set up to realise a yarn processing of low and equalised tension. The yarn passes storage feeders to relax from tension variations arising from the spinning process and the draw off during knitting. The next step is the active pull off support by pre - accelerating the yarn by means of a continuously running friction feed wheel before getting into the actual loop formation area.
The yarn tensioning is implemented by a vacuum device which gently draws back the yarn at moments when the carriage changes its way or when the yarn is not processed.
In addition a special yarn feeder is in use for the weft insertion of the elastan thread. This yarn feeder system works synchronously to the movement of the carriage and is able to block the yarn feeding at moments when the carriage returns or when the weft is not inserted. Thus yarn migration can be prevented and it helps to attain a constant tension within the fabric. The weft insertion feeder can be shifted up and down to prevent any collision and to contribute to a flat selvage formation, which helps at the subsequent sewing process.

Pressure garments for hypertrophic wound care

Particularly following the care of burnt skin areas pressure textiles or garments have proven their effectiveness regarding the curing and development of scars. The generated pressure on the concerned skin areas is supposed to help alleviate the itchiness of scars and to control the build-up of serious contractures.

The average pressure level applied to the treated tissue areas are about 25 mm Hg. However there is currently no general standard existing.

There are different qualities of textiles available which are used for pressure garments. The fabrics in use are either warp or weft knitted net structures or similar fabrics as they are used for compression stockings, however in finer qualities. Such qualities are made on machines of gauge E 16 or E 18.
Whereas normal pressure garments are produced in a regular cut and sew operation, flat knitted elastic fabrics are knitted to correct size and shape (fully fashioned) and sewn together in a subsequent step.

The inserted weft can generate a fairly high compression and in combination with the performed shape correctness these types of pressure garments are mostly applied, when a scar is stable enough to stand a higher level of pressure.

Support and sports braces

The same technology which is used for custom – made compression stockings and pressure garments is also applied for the manufacturing of support and sport braces. The ability to knit to shape allows the production of articles with a perfect fit following anatomic measurements and offering the possibility to ensure a product with an even elasticity or with areas of varying pressure.

These types of products are normally used for supporting and protecting joints at the various zones of the body. The most common areas of application are as:

- knee braces
- wrist braces
- ankle braces
- elbow braces
- shoulder braces
- back support belts

These braces are either worn prophylacticly or for therapeutical reasons. Their medical application normally occurs at:

- post – operative or traumatic irritations
- swelling of joints and articular capsules, i.e. at arthrosis or athritis
- weak or instable ligaments
- specific problems of the various joints

The benefits of flat knitted braces lie in:

- the anatomical shapes which guarantee perfect fitting
- the supporting and compressing effect due to the two way stretch construction
- structural pattern effects for specific qualities and Jacquard design for product identification
- the integration of viscous-elastic profiles or pads for stabilisation, support and massage effects to improve blood circulation and the absorption of haematoms and oedemas.

Since the integration of pockets in flat knitted fabrics is nowadays a kind of a standard for the regular knitwear industry, Stoll incorporated such solutions also in the design of braces to facilitate the production and the making up of these products. Thus braces can contain knit-in pockets for silicon and gel pads or for reinforcement splints.

Stump socks

Depending on their actual use, stump socks normally have a conical shape to fit best on the limb. They are knitted tubularly and are either narrowed or enlarged towards one end of the sock. In comparison to most of the socks produced in the regular sock industry, the stump socks have a closed toe and can be produced completely on the flat knitting machine. Most of the time several socks are produced parallel to speed up the production. The gauge range nowadays varies and starts with relatively coarse gauges of E 7 or E 8 and reaches up to E 12.
The most critical area at the production of a stump sock is the formation of the selvages. They tend to be bulkier and show small openings at courses, when the tube is enlarged or narrowed. These irregularities can cause irritations while wearing a prosthesis.

To encounter these problems, particular stitch sequences are applied at the selvages or additional transfer and split stitch operations are used to cover the openings. New machine developments, such as the machine with additional transfer beds (Stoll CMS 330 TC4) might be of advantage for such a kind of application.

The fiber material used for stump socks are soft, woollenlike qualities which are shrunk and felted in a subsequent process. Relatively new are socks out of modern fibers such as Coolmax® from DuPont. These types or fibers show a high degree of elasticity and physiologic comfort. Most of the time these socks are coated with a layer of cooling and softening polymer gel, impregnated with mineral oils for smoothening the skin. These socks are particularly worn by active people with amputated legs.

SPACER FABRICS

Due to their specific qualities spacer fabrics have recently encountered lots of interest from many different areas of application. The range reaches from use as composite textiles and particularly cushioned seat covers to specific medical applications.

The strength of these fabrics are:

- the thickness, which can specifically be designed, depending on the gauge of the machine and the material selection (i.e. 4 – 4.5 mm of thickness for a fabric coming from a machine of gauge E 14)
- the different degrees of softness, which can be set in dependence of the angle of the inlaid tuck stitch and the chosen material
- the special fabric construction, which allows an excellent drapability; the fabric tends to keep the form, it is brought in

- the various materials, which can be chosen for the outer fabric sides and the connecting tuck inlay
- the shaping ability: similarly to the regular fully fashioned knitwear pieces, the spacer fabrics can also be knitted to shape

Based on these particular qualities the applications as medical textiles can be:

- cushioning elements for orthopaedic use
- support fabrics in casting elements, which are used to support and fix broken limbs in defined positions
- incontinence pads made out of superabsorbent fibres and integrated in fully fashioned pants
- special, ready to wear bandages with impregnated areas of curing emulsions and ointments

IMPLANTS

Based on open mesh constructions some special fibre materials have been processed for pocket - like fabrics which can be used as implants for special applications in the area of abdomen surgery. Possible applications are:

- suspension and protection of the small bowel against injuries during radiation therapy after surgery for pelvic malignancies
- repair of traumatically injured spleens or other soft organs by compression encapsulation

Depending on the actual use the processed materials can consist of non-absorbable fibres such as PP, PA, PES, PTFE yarns as well as of fine stainless steel wires or of bioabsorbable fibres such as polyglycolic acid (PGA) or polylactic acid (PLA).

Until now warp knitted or leno woven mesh fabrics have been used for such applications. However the ability to produce finished bag - like textile structures with a certain elasticity opens up new ways to use these types of fabrics for specific surgical applications.

OUTLOOK

As described before the flat knitting technology has been able to step out of their original areas of application. The scope of medical textiles which can be produced on flat knitting machines by using the specific advantages of this production system steadily enlarges. Stoll encounters the challenges which rise out of these new domains and supports the industry and the research for new medical textiles with particular qualities.
A comprehensive range of flat knitting machines, the continuous development of the machine technology and a far reaching expertise in knitting know how will help to support this goal.

REFERENCES:

1. Dr. Roland Kressig: Brochure "An Introduction to Phlebology" – Salzmann AG, St. Gallen; Switzerland

2. Bauerfeind – Brochure: "Wirkung ohne Nebenwirkung: Das Therapieprogramm von Bauerfeind" – Bauerfeind GmbH & Co., Kempen; Germany

3. Lisa Macintyre, Carolyn Mitchell; Margot Baird and Philip Weedall: "Elastic fabrics for the treatment of hypertrophic scars – comfort and color"; Technical Textiles International, April 1999, page 19 –22; Witney; United Kingdom

4. Barry L. Dumican: "Bioabsorbable Polymers – An Update on Medical End-Uses" – Davis & Geck – Sherwood; USA; paper presented at the Medical Textiles Conference at the Clemson University on 9/9-10/97, Clemson; USA

5. E. Levadoux, F. Rivault, F. Fabre, V. Boiko-Alaux, J. Chopineau: "How to avoid disembowelments"; TUT; 1er trimestre 1998, #27, page 54 –56; Paris; France

6. Ph. D. S. Adanur: "Wellington Sears Handbook of Industrial Textiles"; Technomic Publishing Company, Inc.; Lancaster, PA - USA

Session 2: Compression and bandaging

7. The Design of Pressure Garments for the Treatment of Hypertropic Scarring Caused by Burns

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Hypertrophic scars

Hypertrophic scars are thickened, hard areas of scarred skin which can become tumerous. They are caused by thermal and/or chemical burns, especially when the skin is destroyed below a critical depth. Functional and cosmetic disability can be marked depending on the site of the burn and the extent of damage. The scars tend to be light in colour and project above the normal level of the skin and the problem is greater for people with darker skins i.e. non-Caucasians.

The normal softening and flattening process can be slow and treatment is mainly by the use of a pressure garment which prevents or minimises the formation of protruding scars. Pressure garments are made using a variety of elastic fabrics and can be simple tubes to fit individual limbs or full garments where the burn extends over a large area of the body and may affect more than one limb. The duration of burn rehabilitation can be as long as 12 months and a pressure garment must be worn continuously. Patients will thus require 2 or 3 garments at a time to allow for laundering. These will generally last for 2 to 3 months when elasticity will have dropped below an effective level.

The design and manufacture of pressure garments has not been perfect because of the range and variability of fabrics available, the different sizes of patients and the method of fitting by therapists. Some hospitals buy in and fit ready-made garments whereas others buy in fabric and make their own garments. It is then left to the experience of the garment maker and fitter to achieve the "correct" pressure level for individual patients. Ready to wear garments will not fit all patients in exactly the same manner and some time-consuming alterations may be required. Variations in cutting techniques by different garment makers would give garments that did not apply the same pressure consistently. Whichever method is adopted it is likely that variation in effectiveness of treatment would result.

The objectives of this work were to investigate the factors known to affect the pressure applied at the skin/fabric interface and the factors relating to comfort in wear. The latter is of particular importance since the garment would be worn continuously for a protracted length of time. These factors include the tensile properties of the fabrics, the fabric curvature when in position, the effect of seams and stitching method and the pressure exerted on human limbs. The ultimate aim was to produce and evaluate a set of rules for appropriate fabric and garment parameters.

Two main types of fabric are currently used for making pressure garments:

1 Firm elastic fabrics containing an elastane yarn. These are usually warp knitted powernet or sleeknit.

2 "Tubigrip" – a circular weft knitted cotton fabric with rubber yarn laid-in, manufactured in tubular lengths of different diameters.

The fabrics containing elastane yarn give firmer pressure and last longer whereas "Tubigrip" garments have greater stretch tolerance and require fewer measurements for proper fitting. The "Tubigrip" garments are thus more suitable for the early stages of treatment, particularly for growing children.

The design and sizing of garments

For consistent treatment the garment should maintain the required pressure on the wound throughout the period of wear.

Laplace's law states that "the pressure developed on a cylindrical surface is directly proportional to the tension (and thus the stretch of the fabric) and is inversely related to the radius of curvature of the cylinder."

Although the body and limb are not truly cylindrical, the Laplace law can be applied to give useful information on which to work. The problem is to determine the percentage of reduction (limb to garment dimension) to give the required pressure at the fabric/wound interface. It will be seen that, to achieve consistently effective and comfortable pressure garments covering various parts of the body, the relationship between garment dimensions and body dimensions must be calculated carefully from the elastic properties of the fabric.

Seams and fastenings

Since the garments are worn continuously, seams should be strong enough to resist relatively high transverse forces over a prolonged period of time. Another important factor is seam extensibility and recovery to allow for body movement during wear. Fastenings also contribute to comfort (or lack of it) in wear. Snap-type and zip fasteners are used most but can be uncomfortable in wear due to being hard and/or rough.

Engineering principles in garment construction

Fabric tensile and recovery properties and seam characteristics are easily and accurately measured by standard methods but the critical factor in determining the effectiveness of treatment is the normal pressure applied to the wound. After an extensive review of various devices, the Oxford Pressure Monitor Mk II was selected for use in this study. It is a microprocessor-controlled monitor designed to measure pressures in the range 0 – 240 mmHg. Pressure is monitored continuously in any of a matrix of 12 cells. The sensor cell was modified to allow a deflated air bag to be introduced at the patient interface. Air was then forced into the bag via a three-way tap and the pressure was measured. A minimum volume of air was used so as not to appreciably deform the interface under investigation.

The instrument was found to be unsuitable for use on rigid surfaces or surfaces with very large radii of curvature but functions accurately at the range of curvatures normally encountered on limbs. Below a radius of curvature of 3 cm, however, measurements tended to be inconsistent.

Relationship between fabric curvature, longitudinal tension and interface pressure at wound

It can be shown that:

$$P = (Tx/Rx + Ty/Ry)$$

Where P = pressure produced
Tx = tension per unit length in the x direction
Rx = radius of curvature in the x direction
Ty = tension per unit length in the y direction
Ry = radius of curvature in the y direction

If T is in Newtons/metre and R is in metres then P will be in Pascals.

If the membrane forms the surface of a cylinder, one R will become infinite and the formula becomes:

$$P = T/R \quad \text{(i.e. Laplace's law)}$$

If the membrane forms part of the surface of a sphere, Rx = Ry and the formula becomes:

$$P = 2T/R$$

Whichever formula is used, it is necessary to know the values of T and R to be able to calculate the value of P. R can usually be measured directly and T can be determined from normal load/elongation data obtained from a machine with autographic recording such as an Instron tensile testing machine. The calculated value of P is ultimately compared with the measured value to test the validity of the method.

Fabric particulars

Two fabrics (supplied by Penn International) were used in the bulk of this investigation:

	Fabric 1 Cotton sleeknit #28432	Fabric 2 Powernet #25034
Type	Raschel	Raschel
Gauge	56	56
Weight	270 g/m^2	220 g/m^2
Composition	56 dtex polyamide 450 dtex elastane 100Nm cotton (16%)	67 dtex polyamide 470 dtex elastane
Breaking load	58 kg lengthways 75 kg widthways	60 kg lengthways 48 kg widthways
Breaking extension	360% lengthways 280% widthways	380% lengthways 320% widthways

63 different pressure garments were made based on the sizes of the cylindrical tube models. The circumferences were selected to compare with ranges of leg, thigh, forearm and hand measurements. it was found that the interface pressure reduced (though not in a linear relationship) with an increase in tube circumference and the curves (although of the same general shape) were separate from each other for different percentages of reduction in make-up. It was also found that the pressure test results compared favourably with those calculated from the measurements of fabric tension and radius of curvature. This leads to the conclusion that the method is valid.

The graphs of pressure against the reciprocal of the circumference (Figs 1 and 2) gave straight lines for both fabrics, thus proving that pressure in practice is inversely proportional to circumference.

Fabric # 28432

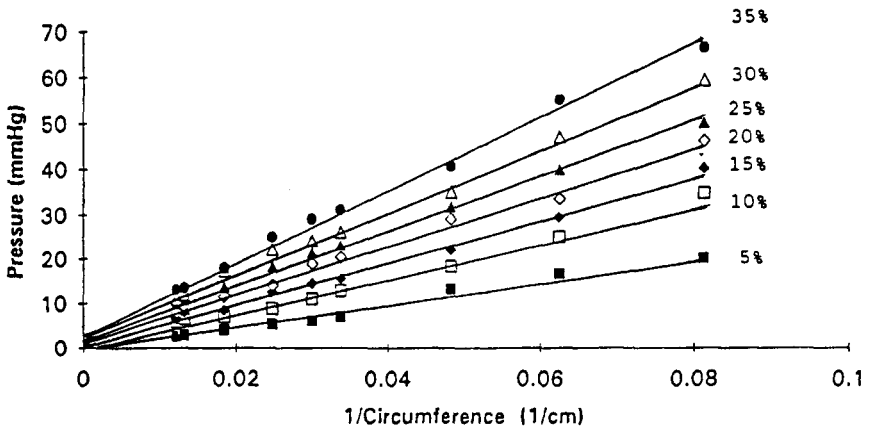

Fig 1

Fabric # 25034

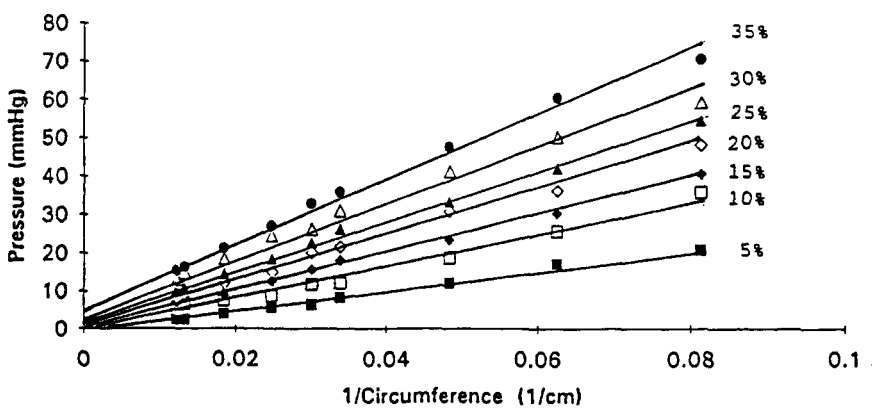

Fig 2

The graphs of fabric tension/circumference against pressure give reasonably straight lines for both fabrics (Figs 3 and 4). Although there were some exceptional results at higher pressures, these pressures are beyond the normal range used in burn rehabilitation treatment (10 - 35 mmHg).

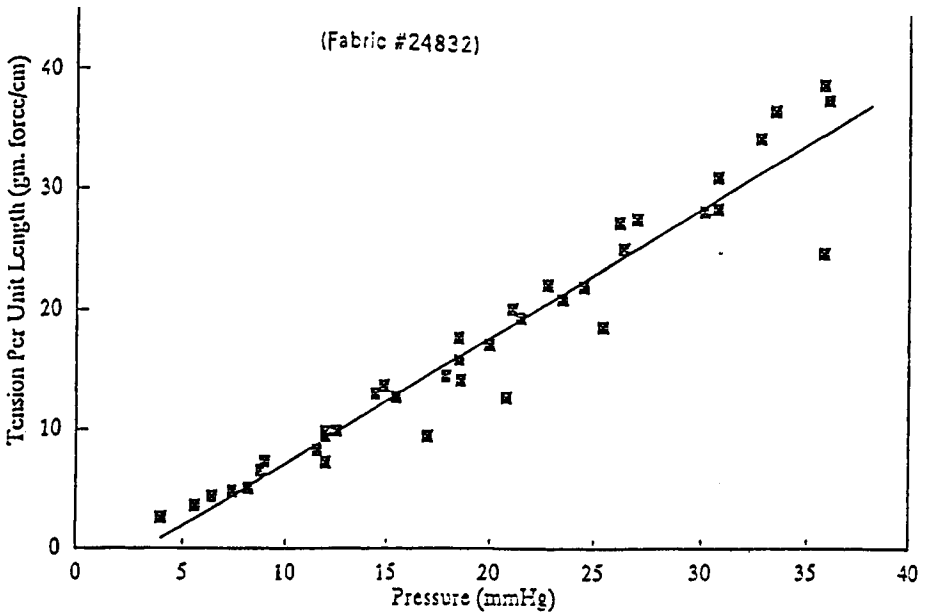

Fig 3

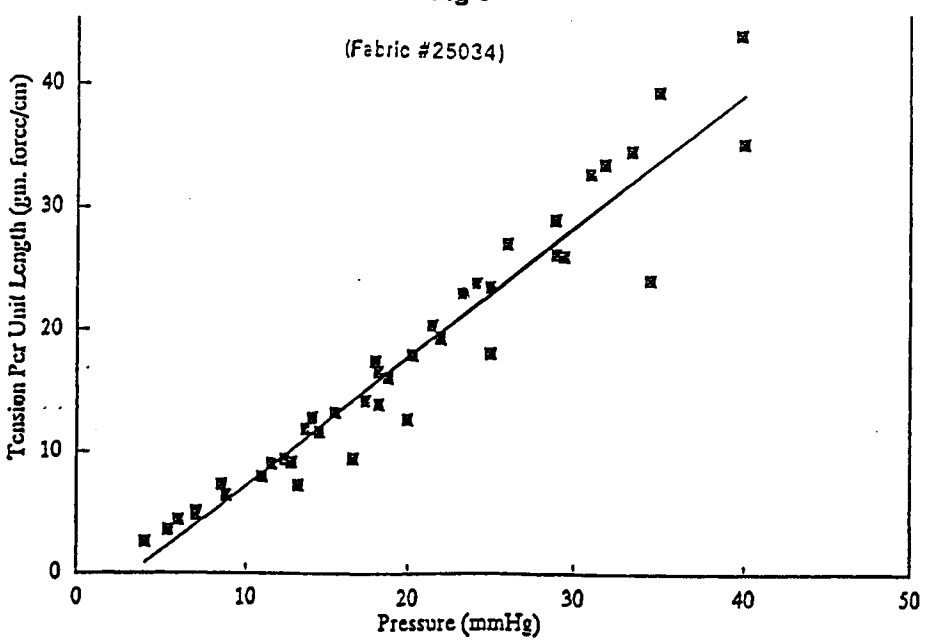

Fig 4

As can be seen from Figs 3 and 4 the lines do not pass through the origin as would be expected. This suggests that there is a residual or contact pressure even when there is zero tension in the fabric and this contact pressure varies with tube circumference.

Discussion

Regression analysis of the experimental results gives the following equation:

$$T/C = A + BP$$

or

$$T = (A + BP)\,C$$

Where T = fabric tension
C = circumference of tube (or limb)
P = pressure
A = intercept on the T axis
B = slope of pressure v fabric tension graph

A and B are constants. The empirical equation derived from experimental results is similar to what would be expected from the theory. The significant difference between theory and experiment is that A is found to be negative whereas in theory it should be zero.

Values of the constant A were found to be:

	Constant A	Constant B
Fabric 1 (#28432)	-3.29759	+1.044743
Fabric 2 (#25034)	-3.39553	+1.058156

Application to human limbs

The experiments carried out using human models rather than limbs gave similar results but there were some differences between the two sets of results. These differences may have been due to human error or to the limitations of the Oxford Pressure monitor used. Alternatively (and this is considered a likely explanation) the difficulty in determining limb circumference accurately may be responsible. The tension applied by the measuring tape can cause limb compression as can the pressure garment itself. Both effects would lead to the accuracy of the measurement being in some doubt.

In order to overcome the practical consequences of the observed differences, suitable corrections were applied which led to a modified formula being developed:

Based on the equation: $T = (A + BP_{tube})\,C$

If $P_{human} = RP_{tube}$

The modified equation becomes $T = (A + BP_{human})\,C$

Where R	=	ratio of slope of pressure curves between the human and tube models
P_{tube}	=	pressure recorded from tube models
P_{human}	=	pressure recorded from human body
C	=	circumference of limb
T	=	fabric tension
A	=	intercept
B	=	slope of pressure v fabric tension graph

Again A and B are constants. In the experiments it was found that the value of R was not constant for every part of the body. For lower limbs a useful working value is 0.95 but, in the case of upper limbs, the value is 0.9)

Wearer reports

The patients who co-operated in the experimental part of the work also agreed to be interviewed from time to time during treatment. In general they were satisfied with the quality of the treatment and the progress made but they all commented favourably on the comfort of the garments during wear.

Conclusion

Although it cannot be claimed that the work has provided a foolproof method of determining the correct dimensions of the pressure garment in all cases it has nevertheless made significant progress. Once the therapist has mastered the calculation it should be possible, provided that fabric data is included in its specification, to improve the quality of treatment provided. At the same time, the skill and experience of the therapist will still be useful.

8. Evaluation of the Pressure Distribution Performance of Padding Bandage Materials

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SUMMARY

The aim of this investigation was to evaluate the pressure distribution and pressure transference characteristics of four commercially available padding bandages. Two instrumental techniques were developed in order to measure pressure distribution accurately. These were the prototype electronic instrument and pressure transference measuring device. The results obtained from the prototype electronic instrument show that the pressure distribution performances of the four padding bandages are very different. In addition, each padding bandage has a distinctive pressure transference characteristic relative to its structure. A number of nonwoven trial fabrics were produced by using different needle-punching techniques, these were then assessed for their pressure transference performance. Based on these test results an optimum padding bandage was developed that exhibits superior pressure distribution characteristics than any of the commercial padding bandages available on the market.

INTRODUCTION

The treatment of venous leg ulcers has been estimated to cost £600m a year and creates considerable demands upon the resources of the NHS[1]. The formation of leg ulcers may be caused by prolonged periods of immobility, paralysis, or other venous disorders[2]. The application of external compression by means of elasticated stockings or bandages serves to increase the velocity of blood flow within the veins by providing support to the calf muscles[3, 4]. The level of pressure exerted on the leg is a function of the tension induced into the compression bandage during application, the number of layers used, and the circumference of the limb. If the compression bandage is applied at a constant tension a pressure gradient is produced whereby higher pressures are exerted on the ankle than on the calf. However, excessively high compression bandage pressures generated over the relatively small radius of curvature of the tibia can lead to the formation of bandage induced ulcers[4,5]. Since there is little subcutaneous tissue at the tibia region the likelihood of this complication is extended further[4]. The requirement to distribute the pressure equally on all points of the lower limb is extremely important. A variety of textile based materials is used beneath compression bandages as padding layers in an attempt to evenly distribute pressure and give protection to the tibia. These types of padding bandage materials can include polyurethane foam bandages and nonwoven orthopaedic waddings. However, there is little published material, which defines their use for this particular application, or whether they have the performance criteria necessary to provide adequate pressure distribution.

EXPERIMENTAL

Materials

The four commercial padding bandages were each given an identification code prior to testing. A description of the padding bandages together with their identification code is given in Table 1. A standard high compression bandage was used throughout this investigation to exert the required level of pressure around the prototype electronic instrument. The manufacturer's recommended tension of 1Kgf was induced into the compression bandage during application, which was then applied with a 50% overlap, or as a double layer.

Prototype Electronic Instrument

The principle of the prototype instrument centres around a mannequin leg and eight foil type strain gauge devices. The leg is used to simulate a real lower limb and has definable tibia, calf, and ankle regions so that compression bandage pressure profiles can be obtained. Each strain gauge device consists of a thin metal foil grid, which is bonded onto a force bearing load beam. The inner dimensions of the leg made it possible to insert a total of eight strain gauge devices at strategic points so that pressure measurements can be made at the tibia, side of the leg, and back of the leg. Compression bandage pressures are detected by means of pressure pins which are connected to each strain gauge device and protrude from the inside of the leg to the outer surface. The construction and arrangement of the pressure sensors are illustrated in Figure 1.
A comprehensive range of tests were designed and undertaken in order to calibrate the prototype electronic instrument. The instrument was calibrated by exerting a range of known pressures (0-160 mmHg) onto each sensor and recording the corresponding measured value. The calibration test results were used to provide statistical evidence to support the accuracy and reproducibility of the prototype electronic instrument. It was found that a highly significant correlation exists between the measured values and the known pressure values for each sensor of the instrument. The relationship between the known and measured pressure values for each sensor of the prototype instrument are shown in Figure 2. The statistical data confirmed that each strain gauge device provides accurate and reproducible results at each measurement point of the leg.

Table 1 - Commercial Padding Bandages

Padding Bandage Code	Description
CB1	All viscose fibre composite, composed of a loose fibre web and two hydroentangled layers.
CB2	All polyester needle-punched and thermal-bonded nonwoven.
CB3	Polyester/polypropylene needle-punched and thermal-bonded nonwoven.
CB4	Polyurethane foam.

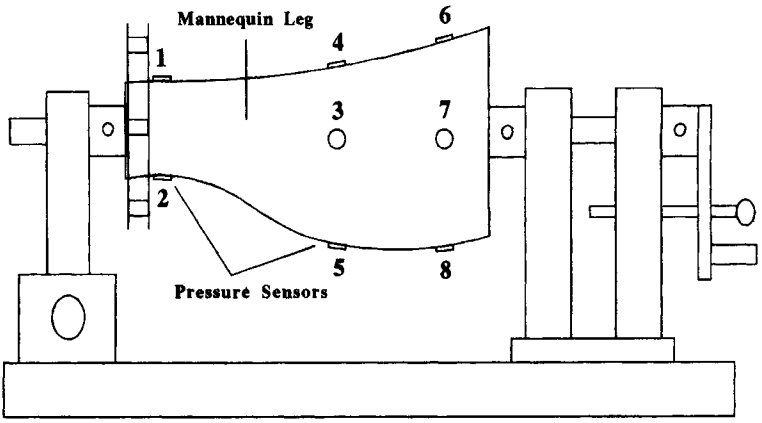

Figure 1 - Prototype Electronic Instrument

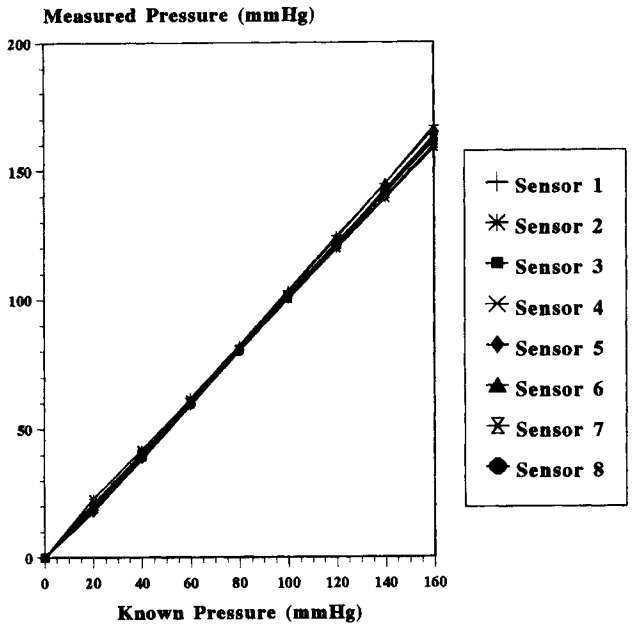

Figure 2 - Pressure Sensor Relationship After Calibration

Theoretical and Actual Compression Bandage Pressures on the Prototype Electronic Instrument

Theoretical compression bandage pressures can be calculated at each measurement point of the prototype electronic instrument by using either one of the following LaPlace equations.

(a) - Based on Limb Circumference: $$P = \frac{(T \times 4630)}{CW} \quad \text{.....Eq. 1}$$

where, P = pressure (mmHg)
T = compression bandage tension (Kgf)
C = limb circumference (cm)
W = compression bandage width (cm).

(b) - Based on Radius of Curvature: $$P = \frac{T}{CW} \quad \text{.....Eq. 2}$$

where, P = pressure (Nm^{-2})
T = compression bandage tension (N)
C = radius of curvature (m)
W = compression bandage width (m)
To convert Nm^{-2} into mmHg units: divide by 133.3

The theoretical pressures based on limb circumference assume the leg to be regular in shape (i.e. a tapered cylinder). Therefore, identical compression bandage pressures are expected on each sensor in accordance to their measurement position on the prototype instrument. In contrast, the theoretical pressures based on limb radius of curvature are calculated by using the actual dimensions of the leg at each sensor position. The theoretical compression bandage pressures based on the two LaPlace equations are shown in Table 2. The theoretical pressures shown in Table 2 highlight the importance of radius of curvature when considering the degree of compression bandage pressure on certain points on the leg. The smaller radius of curvature of the tibia results in higher pressures being generated at the ankle (sensor 1) and below the knee (sensor 6) positions. The tibia at the calf position (sensor 4) is less pronounced and this results in a lower theoretical pressure.

In order to compare the theoretical pressures a reference pressure profile was obtained for the compression bandage by applying it around the prototype electronic instrument. The pressure distribution profile of the compression bandage is compared to the theoretical pressures of the prototype instrument in Table 2. It can be seen that higher pressures are exerted on the areas of the leg where the radius of curvature is small. The theoretical pressure values calculated by the radius of curvature equation are almost identical to the measured pressure profile of the compression bandage. In contrast, the pressure values calculated by the circumference equation somewhat underestimate the actual compression bandage pressures. The prototype electronic instrument has clearly demonstrated the problem associated with compression bandages. Higher pressures are generated on the smaller radii of curvatures and this results in non-uniform pressure distributions around the ankle, calf, and below knee positions of the leg.

Table 2 - Theoretical and Actual Compression Bandage Pressures

Sensor	Theoretical Pressure Based on Circumference (mmHg)	Theoretical Pressure Based on Radius of Curvature (mmHg)	Actual Compression Bandage Pressure (mmHg)
1	51.2	90.8	69.6
2	51.2	115.9	110
3	28.1	31.7	46.7
4	28.1	31.4	40.8
5	28.1	26.7	43.6
6	29.9	50.3	50.8
7	29.9	25.4	28.3
8	29.9	29.7	36.2

The main function of the padding bandage layers is to reduce these high pressures and form uniform pressure distribution around the whole of the lower leg (i.e. from the ankle to just below the knee).

Commercial Padding Bandage Testing on the Prototype Electronic Instrument

The four commercial padding bandages were tested on the prototype electronic instrument to determine their pressure distribution performance. The test procedure adopted for these tests comprised of applying two layers of a padding bandage around the leg of the prototype electronic instrument. A double layer of the compression bandage was then applied over the padding layers and the pressure was recorded via each pressure sensor. The results of these tests are shown in Table 3 where it can be seen that the commercial padding bandages have different pressure distribution performances. None of the padding bandages distributes pressure evenly since high pressures are still exerted on both the tibia and Achilles Tendon areas of the leg.

Pressure Transference Testing

The Pressure Transference test method was designed and developed to measure the pressure which is transferred through a padding bandage structure. By applying a series of known pressures onto the surface of a padding bandage it is possible to measure the resultant pressure which is transferred through the structure to the underlying surface.

The measurement of pressure transference was made possible by designing a test-rig that can be used in conjunction with a Shirley Thickness Gauge. The pressure transference test-rig consists of a wooden platform and a foil type strain gauge device. Padding bandage materials are laid onto the wooden platform over a pressure pin, which is directly connected to the strain gauge device. The known pressures (2.9-26.3 mmHg) are obtained by applying different loads on to the padding bandage surface via the large pressure foot of the Shirley Thickness Gauge. The pressure, which is then transferred through the padding bandage is measured by the smaller pressure pin of the test-rig.

Table 3 - Commercial Padding Bandage Pressure Distribution

	Padding Bandage Pressure Distribution (mmHg)			
Sensor	CB1	CB2	CB3	CB4
1	62.9	49.2	61.7	53.7
2	73.9	77.2	104.7	93.8
3	24.8	34.0	33.4	30.9
4	48.3	34.1	39.5	28.9
5	29.1	34.2	19.9	34.9
6	49.9	41.0	43.2	35.2
7	18.3	22.5	19.6	22.5
8	20.5	30.8	29.8	35.0

The arrangement of the Shirley Thickness Gauge and the Pressure Transference Test-rig is represented in Figure 3.

Pressure Transference of the Commercial Padding Bandages

The pressure transference characteristics of the four commercial padding bandages are shown in Figure 4. An additional line (DPT) is shown which represents direct pressure transference through a padding bandage material. The DPT line is used to judge the effectiveness of a padding bandage in relation to pressure transference and absorption. If the pressure transference trend has a bias toward the DPT line then the ability of a padding bandage to absorb pressure within its structure is limited. In contrast, if the pressure transference trend is close to the base line (X-axis) then a high degree of pressure is absorbed since there is little pressure transferred through the structure.

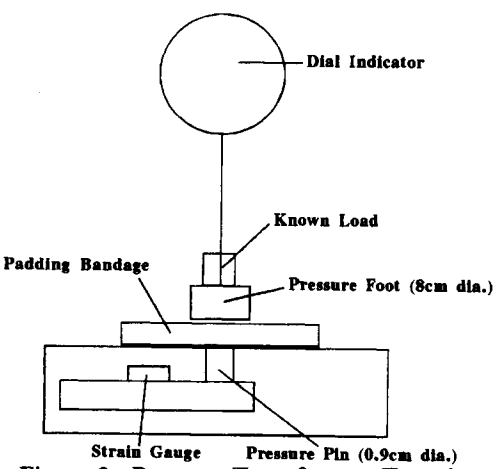

Figure 3 - Pressure Transference Test-rig

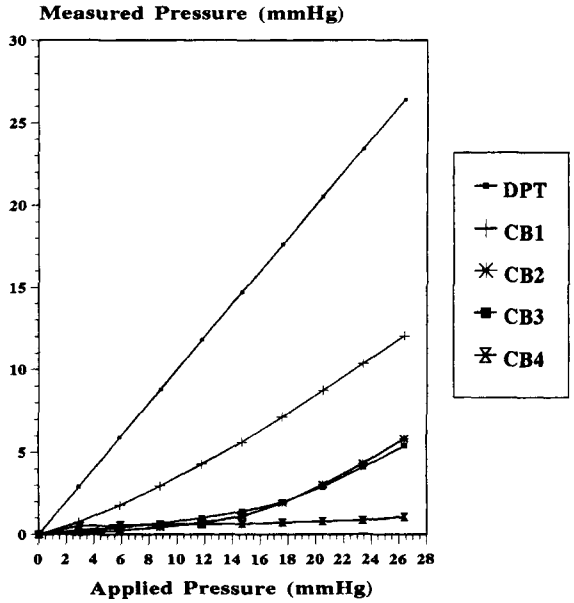

Figure 4 - Commercial Padding Bandage Pressure Transference

It can be seen from Figure 4 that each padding bandage has a different pressure transference characteristic.

The pressure transference trend of the CB1 padding bandage indicates a high proportion of the applied pressure is transferred through the padding bandage to the underlying surface. The physical properties of the CB1 padding bandage are such that pressure absorption by the material is minimal. The poor pressure distribution performance of this padding bandage has been confirmed by its pressure transference characteristic.

The pressure transference of the CB2 padding bandage shows a similar trend to that of the CB4 padding bandage in the applied pressure range (2.9-11.8 mmHg). However, in the range 11.8-26.4 mmHg the pressure, which is transferred is greater for each increase in the applied pressure. The CB2 padding bandage has two pressure transference characteristics where in the initial applied pressure range the structure absorbs a high proportion of the pressure within its structure. In the final applied pressure range (11.8-26.4 mmHg) the reverse is true since a high proportion of the pressure is transferred to the underlying surface.

The CB3 padding bandage has an almost identical pressure distribution characteristic to that of the CB2 padding bandage. In the initial applied pressure range (2.9-11.8 mmHg) the pressure transferred through the structure is slightly lower to that of the CB2 padding bandage. However, as the applied pressure is increased from 11.8 to 26.4 mmHg the pressure, which is transferred is marginally higher.

The pressure transference characteristic of the polyurethane foam CB4 padding bandage is far better in comparison to the other padding bandages. The general trend indicates a high degree of pressure absorption since there is little pressure transferred to the underlying surface. However, the pressure distribution performance measured on the prototype electronic instrument was not as good as the fibre based CB2 padding bandage. A low pressure transference characteristic should result in a good pressure distribution performance. A factor associated with polyurethane foam materials is their high flexural rigidity in contrast to fibre based materials. The inability of the CB4 padding bandage to conform around the lower limb can lead to non-uniform pressure distributions.

DEVELOPMENT OF AN OPTIMUM PADDING BANDAGE MATERIAL

The main objective of this research project was to develop a padding bandage material with far superior pressure distribution characteristics than those of the commercially available padding bandages. A variety of nonwoven trial fabrics were produced by using different needle-punching techniques. Each trial fabric produced was then tested in order to determine its pressure transference performance. It was found that the method and degree of needle-punching has a significant effect on the pressure distribution performance of a fabric. An optimum padding bandage (ASA) was produced during these trials and was found to have excellent pressure transference characteristics.

A comparison between the optimum (ASA) and the four commercial padding bandages, in terms of their pressure transference characteristics, is shown in Figure 5. It can be seen in Figure 5 that the CB4 and optimum (ASA) padding bandages have almost identical pressure transference characteristics. Both padding bandages can absorb and dissipate high pressures within their structure while the pressure transferred through the bandage is minimal.

Pressure Distribution Performance of the Optimum (ASA) Padding Bandage

A large number of tests were conducted on the pressure transference test-rig in order to assess the performance of the optimum (ASA) padding bandage. A statistical analysis was undertaken of the results and it was found that an excellent correlation exists between the applied and measured pressures. The correlation coefficient and linear regression equation for the optimum (ASA) padding bandage are given in Table 4. From the linear regression equation it is possible to predict the pressure distribution performance of the optimum (ASA) padding bandage on the prototype electronic instrument.

In Table 2 it was shown that different compression bandage pressures were recorded at each sensor measurement position of the prototype electronic instrument. It is known that the radius of curvature of the leg has a significant affect on the degree of pressure that is generated by the compression bandage. Therefore, the pressure that is generated at each measurement position is exerted over a specific surface area that equates to the radius of curvature of the leg and the width of the compression bandage. The application of padding bandage layers should, in theory, absorb a certain degree of the compression bandage pressure and produce a uniform pressure distribution around the limb. If the pressure absorption characteristics of a padding bandage were known then it would be possible to calculate its pressure distribution performance.

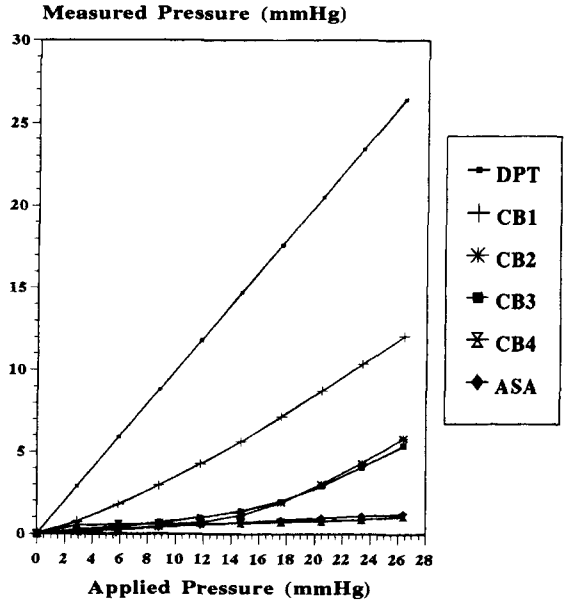

Figure 5 - Optimum (ASA) Padding Bandage Distribution

The pressure transference test method measures the degree of pressure that is transferred through a padding bandage material when a known pressure is applied on to its surface. The difference between the applied pressure and the measured pressure is the amount of pressure that is absorbed by the padding bandage material. The range of pressures that are applied on to a padding bandage are generated over the surface area of the pressure foot of the Shirley Thickness Gauge. From the linear regression equation (shown in Table 4), it is possible to calculate the pressure transference performance of the optimum (ASA) padding bandage for any given applied pressure. Since this is the case, then the degree of pressure absorption and therefore, the pressure distribution performance can also be calculated for the same applied pressure.

The compression bandage pressures that are exerted over the different surface area's (S_1) of each measurement position of the prototype electronic instrument are known (Table 2). If the optimum (ASA) padding bandage was to be placed underneath the compression bandage then it is these pressures that will be applied on to its surface. If the applied pressures (P) are known then the pressure transference, degree of pressure absorption (P_A), and finally, the pressure distribution performance (P_D) of the optimum (ASA) padding bandage can be calculated from the linear regression equation (Table 4). However, the optimum (ASA) padding bandage linear regression equation is based upon the correlation between the applied and measured pressures when a specific surface area (S_2) is used to apply the pressure (pressure transference test method). Therefore, this surface area (S_2) must be related in terms

Table 4 - Statistical Analysis of the Optimum (ASA) Padding Bandage

Correlation Coefficient (r)	**0.9995**
Linear Regression Equation	**y = 0.0465x + 0.0047**

of the surface areas (S_1) of each measurement position of the prototype electronic instrument in order to calculate the pressure distribution performance. The ratio between the surface area (S_1) and surface area (S_2) provides a factor (Sar) by which the different surface areas of the measurement positions can be expressed in terms of the surface area used for the pressure transference test method. When the applied compression bandage pressure (P) is multiplied by this factor (Sar) the resultant pressure value is proportional in relation to the difference between the surface areas (S_1 and S_2). The measurement principle of the pressure transference test-rig is based upon applying known pressures on to the surface of a padding bandage when it is laid flat. However, on application around the prototype instrument the padding bandage is flexed in order for it to conform to the different radii of curvatures of the leg. Therefore, the pressure absorption characteristics of the padding bandage are altered in relation to the degree of flexing over a particular radius of curvature. A correction factor (D_C) is used in Equation 4 in order to account for the difference in pressure absorption when the padding bandage material is flexed as opposed to being flat. The correction factor (D_C) value of 8.4 was obtained from the average difference between the predicted and measured pressure distributions, for all eight measurement positions of the prototype electronic instrument, over a large number of experiments. The following equations were derived in order to predict the pressure distribution performance of the optimum (ASA) padding bandage on the prototype electronic instrument.

$$P_A = \frac{P \times Sar - (0.0465 \times P \times Sar + 0.0047)}{P \times Sar} \times 100 \quad \text{.....Eq. 3}$$

where:
P_A = Pressure absorbed by the padding bandage (%),
P = Applied compression bandage pressure (mmHg),
Sar = Surface area ratio ($S_1 \div S_2$).

$$P_D = \left\{ (P \div P_A \times L) \times 100 \right\} + D_C \quad \text{.....Eq. 4}$$

where:
P_D = Pressure distribution (mmHg),
P = Applied compression bandage pressure (mmHg),
P_A = Pressure absorbed by the padding bandage (%),
L = Number of padding bandage layers,
D_C = Correction factor 8.4.

The predicted pressure distribution values for the optimum (ASA) padding bandage are shown in Table 5. In addition, a series of tests were conducted in order to determine the actual measured pressure distribution performance of the optimum (ASA) padding bandage

Table 5 - Optimum (ASA) Padding Bandage Predicted and Measured Pressure Distribution

Sensor	Predicted Pressure Distribution (mmHg)	Measured Pressure Distribution (mmHg)	Difference Between Predicted and Measured (mmHg)
1	45.0	48.2	-3.2
2	66.3	40.5	+25.8
3	32.7	24.0	+8.7
4	29.9	31.7	-1.8
5	31.3	28.5	+2.8
6	34.8	38.8	-4.0
7	23.3	20.1	+3.2
8	27.5	23.6	+3.9

on the prototype electronic instrument, the results are shown in Table 5. It can be seen in Table 5 that there is a difference between the predicted and measured pressure distribution values for each sensor measurement position of the prototype electronic instrument. At each sensor measurement position, except sensor 2, the differences between the predicted and measured pressure distribution values are minimal and are not considered to be to significant. The radius of curvature at the sensor 2 measurement position of the leg is relatively small since it represents the Achilles Tendon area of the ankle. Therefore, it is expected that higher compression bandage pressures will be generated and exerted on this particular area of the leg. The predicted pressure distribution value correctly forecasts this high compression bandage pressure. The measured pressure distribution value however, is much lower than expected at this measurement position of the prototype electronic instrument. It should be taken into account that it is difficult to maintain the correct compression bandage tension when applying the bandage around this area of the leg. This leads to a degree of experimental error between each test undertaken, due to the different compression bandage pressures that are generated at this measurement position. At all the other sensor measurement positions of the prototype electronic instrument the compression bandage tension is easier to maintain due to the overall shape of the leg. Therefore, experimental error is reduced since the compression bandage pressures that are exerted on these sensor measurement positions are consistent in each test undertaken.

The pressure transference test method provides an accurate determination of the pressure transference and pressure absorption characteristics of a padding bandage material. The more important pressure distribution performance of a padding bandage, can be predicted if the pressure absorption characteristics are known.

CONCLUSIONS

The prototype electronic instrument has provided an effective method by which padding bandage materials can be assessed for their pressure distribution performance. The physical shape and dimensions of the mannequin leg are such that compression bandage pressures are comparable to those exerted on a real limb. An accurate prediction of compression bandage pressures can be obtained from the LaPlace equation based on

radius of curvature. The alternative equation based on limb circumference does not take into account the actual shape of the leg and this results in underestimated compression bandage pressures.

The pressure transference test procedure provides a method by which the pressure transference and absorption characteristics of a padding bandage material can be assessed. In the case of the fibre based padding bandages (CB1, CB2, and CB3) the pressure transference characteristic relates directly to the pressure distribution performance. The CB1 padding bandage has been found to have the worst pressure distribution performance and this has been confirmed by the pressure transference test. The CB4 polyurethane foam padding bandage has the best overall pressure transference characteristic but this does not concur with its pressure distribution performance. A reason as to why this may be the case has been attributed to the relatively high flexural rigidity of the CB4 padding bandage, as compared to fibre-based padding bandages.

None of the commercially produced padding bandages investigated in this work provide uniform pressure distributions around the limb. The structure of a padding bandage has been found to be an important factor which influences the overall pressure distribution performance. It can be concluded that since the CB2 and CB3 padding bandages are composed of inter-connecting fibres they exhibit a degree of resistance to the applied pressure. In addition, the applied pressure is absorbed within the padding bandage structure since it is distributed from fibre to fibre. In the case of the loose fibre based padding bandage (CB1) the application of pressure culminates in the displacement of the fibres relative to one another. It follows that an increase in pressure results in an even greater number of fibres becoming displaced which reduces the degree of support. The pressure that is applied onto the surface is, therefore, directly transferred through to the underlying surface.

The main objective of this research project was to produce a padding bandage material with a superior pressure distribution performance. The unique structure of the optimum (ASA) padding bandage has the ability to absorb a large proportion of the pressure that is applied on to its surface. The pressure that is transferred through to the underlying surface is therefore, greatly reduced. The pressure distribution performance of the optimum (ASA) padding bandage is far superior than those of the other fibre-based commercial padding bandages.

REFERENCES

1. Anon. *Drug and Therapeutics Bulletin*, 1991, **29**, 5, 97-100.
2. S.D. Blair. et al. *Br. med. J.* 1988, **297**, 1159-1161.
3. C.P. Holford. *Br. med. J.* 1976, **2**, 969-970.
4. J. Dale. et al. *Nursing Times*, Nov. 1983, 49-51.
5. M.J. Callam. et al. *Br. med. J.* 1987, **295**, 1382.

9. Elastic Fabrics for Use in Pressure Garments – Comfort Properties

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INTRODUCTION

Hypertrophic scars frequently develop following serious burn injury or other wounds healing by second intention (i.e. wounds whose edges cannot be sutured together). These scars are unsightly, uncomfortable and may lead to scar contracture (areas of contracted skin over flexor joints which reduce the range of motion) if untreated (1,2,3).

Pressure garments have been used in hospitals world-wide to prevent and treat hypertrophic scars since the 1970s. The popularisation of this method of treatment is most commonly attributed to the work done by Larson et al at the Shriners Burns Institute at Galveston in Texas (4). The rationale for pressure therapy is based on the belief that pressure reduces collagen production within the developing or active scar. This belief is backed by years of medical experience and many case studies but has never been scientifically proven. Pressure garments additionally often alleviate the pain or itchiness associated with hypertrophic scars and tend to prevent the development of serious contractures

Pressure garments are normally custom-made from elastic fabrics and are designed to exert a pressure of approximately 25 mmHg on the underlying tissue. This 'ideal' pressure has varied over the years and has never been scientifically established. This appears to be due to the difficulties in applying even pressure to the human body and the lack of actual garment/scar interface pressure measurement in most hospitals. The efficacy of this treatment and the fit of garments is normally assessed subjectively based on individual practitioner's experience. Some work has been conducted on garment/scar interface pressure (5) but no conclusions on the most effective pressure were drawn, much of this research being concerned with developing accurate means for pressure measurement.

There are several problems associated with current pressure garment treatment. Fundamental problems in treatment delivery include:

1. lack of scientifically established procedures for safe/effective pressure therapy (6, 7);
2. blistering and scar breakdown may occur if too much pressure is applied too soon, resulting in treatment suspension (8, 9);
3. pressure is difficult to apply evenly, particularly in concave areas of the body (8, 9);
4. applied pressure varies with time and movement and the precise nature of these changes has not been measured fully.

There are other problems which also affect patient treatment. These problems commonly lead to patient non-compliance with their treatment, often resulting in treatment failure, and include:

A. discomfort from heat and sweating, particularly in warm weather (7, 10);
B. wide ranging skin problems brought on by pressure garments in some children (11);
C. poor appearance and inappropriate colour of pressure garments (10, 12).

The purpose of this study was to characterise the fabrics currently used in the manufacture of pressure garments and address some of the aforementioned problems. The work presented here was mainly concerned with problem A and to some extent

problem B. Point C was dealt with in a previous publication (13) and points 1 to 4 will be investigated in future work.

CHARACTERISATION OF ELASTIC FABRICS USED IN THE CONSTRUCTION OF PRESSURE GARMENTS

Methodology

18 knitted fabrics currently in use in the manufacture of pressure garments were gathered from 6 suppliers in both Europe and the USA. The basic determinant characteristics and elementary properties of all these fabrics were assessed. This was necessary as the fabrics were supplied with varying levels of specification detail and it was apparent that different methods had been used to establish even the most basic properties of the fabrics. The following procedures were used in this study:

- structures were established according to BS 5441:1988;
- wales and courses per cm were counted in accordance with BS 5441:1988;
- percentage fibre composition was established according to BS 4407 : 1988 Section 3;
- the count of the elastane yarns (in tex) in situ was established using a method based on Section 2, Part 7.2 of BS 5441 : 1988. Five samples of each fabric were measured and the sample length was taken as 200 mm, the length of the elastomer while still in the fabrics;
- mass per unit area was established using 3 (200 x 200 ± 1 mm square) samples of each fabric and an average was calculated (in g/m^2);
- thickness (in mm) was found following BS 2544:1987, using a pressure of 1 kPa applied to a sample area of 10 000 mm^2;
- fabric density (in kg/m^3) was calculated by dividing the mean mass per unit area of each fabric by its mean thickness;
- the elastic modulus (in N/m) of 20 x 20 cm looped specimens (BS304 seam) was measured after a single 5 minute 25% extension in accordance with BS4952 : 1992.

Results and discussion

Twelve of the fabrics were found to be warp knitted powernets, three were warp knitted sleeknits, two were weft knitted 1 x 1 ribs and one was a plain single weft knitted fabric. In the referencing system for fabrics which follows, the fabric reference numbers were prefixed with a 'p' for the powernet fabrics, 'n' for sleeknit, 'r' for rib structures and 's' for the plain single weft knit. As can be seen from the fabrics supplied for this study (Table 1) the powernet structure is the most commonly used in UK hospitals. Most custom-made pressure garments in the UK are made from powernet fabrics, whether made internally by occupational therapists or externally by specialist manufacturers. The sleeknit structure is commonly used for treating particularly fragile scars, for example in the initial stages of pressure treatment in children. Fabric r16 is supplied in tubular form and is commonly used as an interim garment until custom-made garments can be fitted, but this fabric is no longer recommended by the supplier for this end-use, although it may still be used in hospitals. Fabrics r17 and s18 are very unusual since they are knitted to the correct size and shape for the patient by the fabric/garment manufacturer. These are not currently commonly used in the UK.

Table 1 - Determinant characteristics of pressure garment fabrics

	p1	p2	p3	p4	p5	p6	p7	p8	p9	p10	p11	p12	n13	n14	n15	r16 *	r17	s18
nylon (%)	64.8	64.5	64.7	65.4	60.3	60.2	60.8	60.8	76.1	88.2	81.4	74.1	60	49.2	48.8	8.4	90.1	72.2
elastane (%)	35.2	35.5	35.3	34.6	39.7	39.8	39.2	39.2	23.9	11.8	18.6	25.9	11.3	31.1	31.6	11.8	9.9	27.8
cotton (%)	0	0	0	0	0	0	0	0	0	0	0	0	28.7	19.7	19.6	79.8	0	0
elastane (tex)	41	41	41	41	55	57	57	53	40	22	35	43	14	47	48	163	41	65
wales/cm	16.6	17	17.2	17.1	17.3	16.6	16.8	16.9	14	13.7	14	14.7	14.7	15.5	15.5	12.3	7.4	10.3
courses/cm	73.7	71.8	73.9	73.2	78	76.3	78	75.6	71.5	61.2	58.1	46.5	13.9	13.6	14.1	9.2	10.2	17.3

Table 2 - Elementary properties of pressure garment fabrics

	p1	p2	p3	p4	p5	p6	p7	p8	p9	p10	p11	p12	n13	n14	n15	r16	r17	s18
thickness mm	0.39	0.41	0.4	0.44	0.45	0.45	0.48	0.42	0.48	0.5	0.51	0.5	0.53	0.61	0.61	1.42	1.33	1.02
mass g/m^2	195	205	212	216	243	244	250	233	236	263	276	249	175	240	245	332	424	396
density kg/m^3	498	506	529	492	537	541	523	556	488	530	538	500	329	395	400	235	318	388

As can be seen from Tables 1 and 2 the powernet fabrics had the greatest density both in terms of the number of stitches per centimetre and mass per unit volume compared to the other structures. They were also the thinnest of the fabrics tested. The number of variables in these fabrics was such that no determinant characteristic could be held responsible for increasing the thickness, mass or fabric density of all the powernet fabrics.

The sleeknit fabrics were less dense and thicker than the powernet fabrics. Although only three sleeknit fabrics were tested it could be seen that the dominant variable affecting most of the properties of these fabrics was the elastane count. Increasing the elastane count has been shown to increase the fabric thickness, mass per unit area and density (mass per unit volume).

The weft knitted fabrics r16-s18 were included in this study in order to complete the survey of fabrics currently used in the treatment of hypertrophic scars. However, there were too few fabrics and too many determinant variables to draw any meaningful conclusions. Note, r16 contained elastodiene not elastane.

The elastic modulus of these fabrics is extremely important as it is one of the major contributing factors to affect the pressure exerted by pressure garments on the skin/scar. Fabrics with high elastic moduli will exert more pressure on the skin than those with low elastic moduli, assuming fabric extension, garment construction, radii of curvature and underlying tissue are constant.

Most of the powernet fabrics would, therefore, exert more pressure on underlying tissue than the sleeknit fabrics if similar garment construction techniques were used. The differences between fabrics of the same structure appeared to be largely due to the different quantities/qualities of elastomeric yarn present. The relationships between increasing elastomeric yarn content (by mass per unit area, percentage or count) and increasing elastic modulus were very clear for the powernet fabrics but further study, with more fabrics, would be required to confirm these trends for the sleeknit fabrics. The weft knitted fabrics r16 and r17 are not used in the same way as the warp knitted fabrics in pressure garment construction, so comparison between warp and weft knitted fabrics would be inappropriate. There was not enough of fabric s18 to allow measurement of its modulus.

Table 3 - Elastic modulus (in N/m) of looped specimens measured at 25% extension

	p1	p2	p3	p4	p5	p6	p7	p8	p9	p10	p11	p12	n13	n14	n15	r16	r17
modulus N/m	47	51	52	48	65	62	64	59	38	30	42	60	13	37	34	8	28

PROPERTIES RELATED TO THE COMFORT OF FABRICS USED IN PRESSURE GARMENTS

Pressure garments must be worn for 23.5 hours per day for between 9 months and more than 2 years, so it is essential that they are comfortable to wear. They must not abrade the developing scar or adjacent skin, which is either covered by, or in contact with, the pressure garment. They should not cause physiological discomfort due to excess warmth or sweat production. Therefore, following the initial assessment of the constructional and elementary properties of these fabrics, properties contributing to their thermophysiological and sensorial comfort were assessed.

Methodology

All tests were performed on conditioned samples in their relaxed state under standard laboratory conditions. Since there were distinct differences between the two surfaces of most of the fabrics they were arbitrarily labelled face and reverse based on a subjective assessment of their roughness. Fabric reverse appeared to be less rough than fabric face.

- The thermal resistance (in togs) of the fabrics was measured on the Zweigle Alambeta T675. The temperature difference between the 'hot' and 'cold' plates was 10K and a pressure of 1 kPa was applied. 10 samples of each fabric were tested.
- The water vapour permeability index (WVPI) of the fabrics was assessed in accordance with BS 7209 : 1990. The test duration was 23 hours in each case. Additional control dishes were prepared with no fabric for comparison with the reference fabric.
- The fabrics' air permeability (in mm/second) was tested in accordance with BS EN ISO 9237 : 1995. The test area was 5.07 cm^2, the guard ring and vent valve were closed. 10 samples of each fabric were measured at a pressure of 4 mm of water (39.2 Pa).
- The rate of wicking (in mm/minute) was established following a method based on BS 3424 : 1986, Part 18. The samples were modified by moving their suspension point to 120 mm above the base line and another line was drawn across the samples 100 mm from the base line. The time taken for the dye liquor to be wicked from the base line to the second line was measured and rate of wicking was calculated. If after eight hours the dye had not reached the second line the distance wicked was measured and rate of wicking calculated. Two walewise and 2 coursewise samples of each fabric were tested.
- The KES-FB-4S Surface Tester was used in accordance with the instruction manual to measure the fabrics' surface roughness (smd in μm), coefficient of friction (miu) and mean deviation of friction (mmd). The minimum tension of 200g was applied to hold each fabric sample in position. 3 samples of each fabric were measured in 3 different walewise and coursewise positions on both fabric face and fabric reverse of each sample. This gave a total of 18 results on fabric face and 18 results on fabric reverse, for each parameter on each fabric.

Results and discussion - effects of structure on properties related to thermophysiological comfort

It is generally considered more comfortable for pressure garments to have low thermal resistance so that the wearer may have normal control over their body temperature. The

Table 4 - Properties related to thermophysiological comfort

	p1	p2	p3	p4	p5	p6	p7	p8	p9	p10	p11	p12	n13	n14	n15	r16	r17	s18
thermal resistance togs	0.12	0.12	0.12	0.13	0.12	0.12	0.13	0.13	0.14	0.14	0.14	0.14	0.16	0.17	0.17	0.29	0.27	0.22
WVPI	99	98	99	98	97	96	97	103	98	96	96	100	102	98	98	96	89	95
air permeability mm/sec	the powernet fabrics were too permeable to be tested												180	188	183	322	126	20
wale wicking mm/min	0.13	0.14	0.16	0.2	0.12	0.19	0.09	0.13	1.12	0.26	0.66	0.96	8.33	3.71	8.01	0	5.61	0.69
course wicking mm/min	0.17	0.16	0.18	0.21	0.12	0.21	0.16	0.2	1.29	0.19	0.42	0.54	6.07	2.04	5.41	0.11	5.12	2.29

weft knitted fabrics had higher thermal resistance than warp knitted fabrics. Sleeknits had higher thermal resistance than the powernets. Therefore in terms of relative warmth, powernet fabrics would affect body temperature least and weft knitted fabrics most.

High water vapour permeability indicates that perspiration would evaporate off the skin unhindered, and high rates of wicking would transport moisture by capillary action away from the skin, making the pressure garment more comfortable to wear. However, there is some evidence to suggest that occlusion (moistness) of the scar may be beneficial to the maturation (overall healing) process, therefore poor wicking and permeability to moisture vapour may be efficacious.

The water vapour permeability test method was not sensitive enough to establish differences between these fabrics. Additionally, it was not ideal for measuring fabrics which are worn next to the skin. All these fabrics had approximately similar WVPIs to the reference fabric, i.e. they allowed approximately one third of the vapour to evaporate through them when compared to similar tests with uncovered control dishes. Therefore these fabrics would be likely to increase sensible perspiration compared to no fabric, but no single structure was significantly better or worse than any other. However, if the average WVPI was taken for each structure, the weft knits would have lower WVPIs than the warp knitted fabrics.

The rate of wicking test showed that the powernet fabrics had the lowest wicking rate, while on average the sleeknits had the highest wicking rate. Although this type of wicking test is the only one available for use, it was not really appropriate since it measured edge wicking and not through-fabric wicking. No method for determining through-fabric wicking, as normally occurs in clothing fabric, has been established. Further work in this area is required.

The air permeability test was conducted as an indication of how porous the fabrics were. Low air permeability would normally be considered most appropriate for pressure garments. The powernet fabrics were so permeable to air that they could not be assessed using this method since it was impossible to achieve the equipment's minimum pressure drop consistently across these fabrics. Of the remaining fabrics the two denser weft knitted fabrics had the lowest air permeability, the sleeknits had medium air permeability and the least dense of these fabrics (r16) had the highest air permeability.

Based on the results of these tests it may be concluded that the powernet structure, having the lowest thermal resistance and air permeability of the structures tested and having reasonable water vapour permeability, may cause the least disturbance to the body's thermophysiological balance. The weft knitted fabrics would probably have the most noticeable, detrimental effect on the thermophysiological comfort of the garments.

Results and discussion - effects of structure on the surface characteristics

Each surface characteristic was measured in 2 orientations 18 times on the face and 18 times on the reverse of each fabric in the study. The means and standard deviations of

these results are presented in Table 5 below. There was considerable variation between many of the results, this occurred for a number of reasons:

- different fabric orientations had different surface characteristics due to their structures not being balanced (as is typical of knitted fabrics);
- the equipment was extremely sensitive and measured only small areas of fabric at a time;
- no properly collected results were discarded – the operator manual suggests discarding the least similar result of every 4 measurements taken.

Fabrics with low coefficients of friction are likely to be considerably more comfortable than those with high friction and they would be less likely to cause maceration (scar breakdown). It can be seen from the mean results presented in Table 4 that the:

- weft knitted fabrics had more friction than the other structures on both face and reverse;
- sleeknit fabrics had medium friction on both face and reverse;
- powernet fabrics had the least friction on both face and reverse;
- reverse of the two warp knitted structures had less friction than the face;
- level of friction measured in the sleeknit and powernet fabrics was within the normal range for clothing fabrics. The friction measured in the weft knitted fabrics was exceptionally high.

Mean deviation of coefficient of friction is a useful measure since it is likely that friction may be better tolerated if it is consistent. The results indicated that the:

- powernet fabrics had the greatest frictional deviation on the fabric reverse;
- weft knitted fabrics had medium frictional deviation on their reverse;
- weft knitted fabrics and powernet fabrics had similarly high mean frictional deviation on their face;
- sleeknit fabrics had the least frictional deviation of all the structures on both surfaces.

Surface roughness is a measure of the peak to trough distance of the fabric's surface and is measured in micrometres. Surface roughness varies considerably between fabrics and increased roughness does not necessarily lead to decreased sensorial comfort. The mean results presented in Table 3 indicated that:

- all the fabrics were rougher on their face than they were on their reverse;
- the powernet fabrics had the greatest surface roughness of the three structures on both face and reverse and their coursewise roughness was considerably greater than their walewise roughness particularly on their face;
- the weft knitted fabrics had medium surface roughness;
- the sleeknit fabrics had the least surface roughness on face and reverse.

These results indicate that the surface characteristics of the reverse of the warp knitted fabrics would be more tolerable next to the skin than the face. Since the scar is

Table 5 - Mean surface characteristics of structure face and reverse

	coefficient of friction				mean deviation of friction				surface roughness (μm)			
	fabric face		fabric reverse		fabric face		fabric reverse		fabric face		fabric reverse	
	mean	S.D.	mean	S.D.	mean	S.D.	mean	S.D.	mean	S.D.	mean	S.D.
powernet	0.226	0.028	0.22	0.024	0.038	0.021	0.038	0.019	9.016	7.026	7.44	4.495
sleeknit	0.268	0.021	0.25	0.034	0.026	0.013	0.022	0.014	6.294	4.051	4.974	3.908
weft knit	0.347	0.05	0.356	0.046	0.039	0.017	0.034	0.006	6.542	2.549	6.355	2.563

likely to be more sensitive than adjacent skin the fabric reverse may be more suitable than the face as the scar contact surface. It is therefore recommended that fabrics should be labelled face and reverse prior to supply to hospitals.

At this stage it is not known whether patients wearing garments made from these fabrics would perceive these differences in surface friction and roughness. This will be verified by wearer assessment of the comfort of pressure garment sleeves later in the study. This will allow all the factors affecting sensorial comfort to be taken into account, for example increased moisture on the skin is known to increase its sensitivity to roughness.

Results and discussion - links between the determinant characteristics of powernet fabrics and the properties affecting their comfort

Significant increases (more than 5%) in the percentage and mass of nylon per unit area in these fabrics was shown to increase their thermal resistance. However, whether these increases in thermal resistance would be noticed by the wearer is unknown at present.

None of these fabric's measured determinant characteristics had any significant and consistent influence on their water vapour permeability or rate of wicking.

Increasing the courses per centimetre of these powernet fabrics had the effects of decreasing walewise roughness and frictional deviation while increasing the coursewise frictional deviation of both face and reverse. It did not significantly affect any of the other properties. Other relationships existed between the determinant characteristics and both thermophysiological comfort and the surface characteristics. However, further study with specially manufactured fabrics would be required to confirm these findings.

Results and discussion - links between the determinant characteristics of sleeknit fabrics and the properties affecting their comfort

As previously stated the dominant variable that determined all the properties of these fabrics appeared to be the elastane count. Increasing the elastane count in these sleeknit fabrics decreased the fabric's permeability to water vapour. Further, increasing the elastane count appeared to lead to greater thermal resistance due to the increased space this created in the fabric. This could be verified by extending the range of sleeknit fabrics evaluated. Elastane count had no effect on the relative air permeability or wicking rate of these fabrics. Therefore, increasing the elastane count might have a negative effect on the thermophysiological comfort properties of these sleeknit fabrics.

There was some evidence to suggest that increasing the count of the elastane in these sleeknit fabrics decreased the measured coefficients of friction of the fabrics. The effects of this change on the frictional deviation varied between walewise and coursewise measurements therefore no overall benefit could be derived. The effect of varying elastane count on the overall surface roughness was not clear.

LIMITATIONS OF STUDY TO DATE

When this study began there was little published information regarding the types of fabric used in the construction of pressure garments. These fabrics were simply referred to as 'lycra fabric' in most of the literature. Therefore it was decided to gather commercially used fabrics for this study. However, this led to several difficulties, including:

- limited and varied details of fabric manufacturing processes and specification were supplied with the fabrics, these being commercially sensitive;
- some of the fabric variables cannot be divined from the finished fabric and remain unknown, e.g. input tension of elastane;
- the determinant characteristics of the fabrics were not equally and well spaced as they would have been if the fabrics had been designed and made specifically for this study;
- only 3 sleeknit fabrics and 3 weft knitted fabrics were used in UK hospitals at the start of this study, therefore the number of fabrics available for study was limited.

These problems made the analysis of the results difficult and limited the conclusions that could be drawn from them. However, all the results are pertinent to current treatment.

FUTURE WORK

Future work is planned on the subjective assessment of the comfort of pressure garment sleeves using wearer trials and on various factors affecting the garment/skin interface pressure. The garment/skin interface pressure study will utilise Tekscan pressure sensors (14) which are 0.007 inch thick and therefore enable good conformity to the site without affecting the measured pressure.

REFERENCES

(1) I Kelman, B McCoy. 'The Biology and Control of Surface Overhealing'. *World Journal of Surgery* 1980 4 289-295.
(2) P Ehrlich, et al. 'Morphological and Immunochemical Differences Between Keloid and Hypertrophic Scar'. *American J. of Pathology* 1994 145 1 105-113.
(3) B Lamberty, J Whitaker. 'Prevention and correction of hypertrophic scarring in post-burns deformity'. *Physiotherapy* 1981 67 1 2-4.
(4) H Linares, et al. 'Historical notes on the use of pressure in the treatment of hypertrophic scars or keloids'. *Burns* 1993 19 1 17-21. And references therein.
(5) H Giele, et al. 'Direct measurement of cutaneous pressures generated by pressure garments'. *Burns* 1997 23 2 137-141. And references contained therein.
(6) W Reid, et al. 'Hypertrophic scarring and pressure therapy'. *Burns*. 1987 13 29-32.
(7) F Ng. 'Design of Pressure Garments for Hypertrophic Scar Treatment'. PhD Thesis, De Montfort University 1995. And references contained therein.
(8) P Leung, M Ng. 'Pressure treatment for hypertrophic scars resulting from burns'. *Burns*. 1980 6 244.
(9) J Collins. 'Pressure Techniques for the Prevention of Hypertrophic Scar'. *Clinics in Plastic Surgery*. 1992 19 3 734.
(10) B Lamberty, J Whitaker. 'Prevention and correction of hypertrophic scarring in post-burns deformity'. *Physiotherapy* 1981 67 1 2-4.
(11) J Kloti, J Pochon. 'Conservative treatment using compression suits for second and third degree burns in children'. *Burns* 1982 8 80-187.
(12) R Thompson, et al. 'Color pressure garments versus traditional beige pressure garments'. *J. of Burn Care and Rehab*. 1992 13 590-596.
(13) L Macintyre, et al. 'A Study of Elastic Fabrics for use in the treatment of hypertrophic scars'. *World Textile Congress, Huddersfield* 1998 319-327
(14) R. Mann, et al. 'A new tool to measure pressure under burn garments'. *J. of Burn Care Rehab*. 1997 18 2 160-163.

10. Methods of Calculation of Local Pressure of Elastomer Products

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Tights and semi-stockings (or knee-length socks) as whole-knitted articles, happened to be most usable for treating chronic venous insufficiency.

The application of knee-length socks is determined by the fact that a varicose phlebectasia and its complications take place much more often on a segment of a shin (anticnemion), and venous blood circulation in the lower extremities is controlled by operation of calf muscles (musculus gastrocnemius).

At present , the produced knitwear manufacture for medical application has considerable short – comings as the body height and weight are criteria for its selection. However, all this does not reflect the efficiency of application of articles in full amount.

There is a necessity to develop a technique providing local pressures, created by a product in various parts of a body according to medical recommendation [1] and to create a mathematical model of pressure of elastomer non-propulsive textile shells, which fulfil these recommendations.

This research is devoted to the solution of these tasks.

Let's consider the basic mechanical and geometrical factors influencing investigated value – pressure.

Solving the task we deal with the distributed forces. This circumstance determines difficulties of measurement of the shell pressure on a body. The distributed forces can be presented as system of infinitesimal forces put to each point of any line or area (see a fig. 1a).

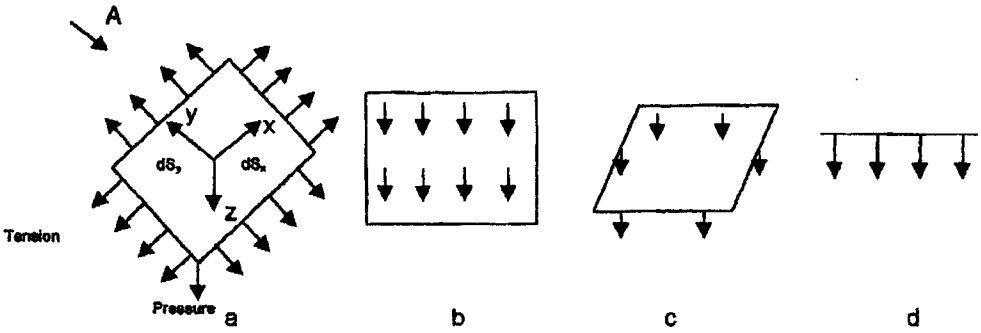

Fig. 1. The distributed forces.

These elementary forces depending on a direction can be tangential (Fig. 1 b) or normal (Fig. 1 c).

To proceed from elementary forces dS_x and dS_y to real forces, they should be integrated on a segment of a line (Fig. 1 d), or on an area of a surface (Fig. 1 b). According to the Theorem Of The Mean [2], let's replace integration by multiplying of value of elementary force in some mean point (segment or area accordingly) by length of a segment or by area of a surface.

Let's consider a system consisting of shell, mounted with some tension on a body and the body, which are interacting among themselves. Let's cut an area around a point which we are interested in (Fig. 2) and according to the principle of the LaGrange, let's replace operation of the discarded parts of the shell by the distributed tension forces put on lines of a segment. Being guided by the same principle, let's eliminate from consideration a support, which is the body, substituting its operation by a support reaction - in this case by elementary forces of the body pressure on the shell which are directed bottom-up, in the opposite direction of the axis z.

On the third Newton's law the shell will press on a body with force, equal on value and opposite on the sign. Their direction is visible in a fig. 2. Omitting vector signs from a fig. 2 it is visible that because of curvature of a surface the elementary forces F_x, as well as F_y form among themselves some infinitesimal angle. Adding them in each point by the rule of a parallelogram, we get elementary pressure force, which is directed downwards, lengthwise axis z, from the shell to a body.

Thus, we've obtained the conclusion, which is important in a qualitative sense: the pressure on a body of an elastomer shell is determined not by only by tension forces operating on a body and connected with mechanical

parameters of a shell, but also by geometry of a body and therefore geometry of a tight-fitting shell.

This outcome can be illustrated on a following example. Obviously, the shell will create pressure only on the curved segments. And if in any area the surface has a concave segment, the pressure of an elastomer shell on this segment will be equal to null. In this case from all geometrical parameters of a body the curvature of a surface only, which can be characterized by a radius of curvature, plays a role.

From above mentioned it is visible, that the mechanism of origin of elastomer shell pressure on a body consists of two parts, one is defined by tension, and other by geometry (curvature) of a body.

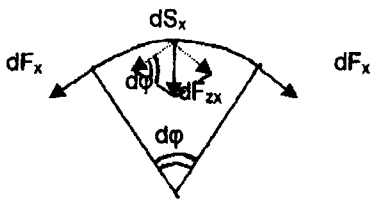

Fig. 2. The efforts in an elastomer textile shell.

The given reasoning allows to divide the basic task (formulated in the beginning of the work) into two subtasks and to plan ways of their solving.

First - geometrical. Knowing the curvature of a surface, we shall get connection between the operating distributed tension forces and pressure. Let's name this task geometrical meaning that the obtained outcome does not take into account mechanical properties of an item or initial material.

The second task - definition of the distributed tension forces arising in a shell when resiliently stretching it on a body. The solution of this task will be grounded on the mechanical characteristics of a product. The tangential distributed tension forces directed lengthways of an elastomer items are considered (see fig. 1) irrespective of the fact how it bent on a body. By virtue of this independence it is possible to consider at research, that the elastomer item is located in a plane, as on a dynamometer for load – lengthening characteristics test.

The second task is in turn divided into two special cases - case of one-dimensional deformation and more complicated - case of two-dimensional deformation.

Let's disassemble a general solution of a geometrical task [3]. We shall consider elementary forces represented in a fig. 2. Let's designate the arcs limiting a cut area as dS_x and dS_y. Then the elementary tension forces on a cut line will be proportional to the lengths of arcs, and force of the shell influence on a body – to the area of an elementary square:

$$\left.\begin{aligned} dF_x &= f_x dS_y \\ dF_y &= f_y dS_x \\ dF_z &= f dS_x dS_y \end{aligned}\right\} \qquad (1)$$

The force dFz can be expressed through dF_x and dF_y, having summed these forces by the rule of a parallelogram. For this purpose it is necessary to know an angle, which do summed forces form. Let's make appropriate calculation for a component, formed by forces (for forces dF_y the conclusion is made similarly). For this purpose we shall look at the area sideways, lengthwise axis y. The radiuses conducted to the edges of the area, will derive among themselves an angle which we shall designate dφ. As the forces dF_x are directed on tangent to a surface and, therefore, perpendicularly to radiuses, the angle between forces also is peer dφ. Via the angle dφ it is possible to define both component dF_{zx} from forces dF_x; and length of an arc dS_x:

$$\left.\begin{aligned} dF_{zx} &= 2 f_x dS_y \sin d_{\varphi/2} = f_x dS_y d\varphi; \\ dS_x &= R_x d\varphi \end{aligned}\right\} \qquad (2)$$

As the angle dφ is infinitesimal, we shall replace value of sine by value of the angle. This value in turn we shall express through R_x and dS_x:

$$\left.\begin{aligned} dF_{zx} &= f_x / R_x \, dS_x dS_y \\ dF_{zy} &= f_y / R_y \, dS_y dS_x \\ dF_z &= dF_{zx} + dF_{zy} \end{aligned}\right\} \qquad (3)$$

Here expression for component on an axis y is written out by analogy with axes x and z. The radiuses R_x and R_y are generally not peer between themselves. Let's compare (1) and (3), we shall get a required ratio:

$$P=f_x/R_x+f_y/R_y \quad (4)$$

From (4) it is visible, that the pressure is direct in proportion to the distributed forces of tension and inversely proportional to radiuses of curvature. The mechanical characteristics of an item - rigidity and Poisson's constant - were not included in required expression.

The simplicity of the formula (4) to a certain extent is apparent, as in practice generally is inconvenient to calculate radiuses of curvature. Therefore we shall consider a particular case: when the body is represented as cylindrical and conical segments.

In this case along rectilinear generatrix of body (leg), the radius of curvature R_y aims at infinity and the formula (4) is simplified:

$$P=f_x/R_x \quad (5)$$

Though the shape of human leg is similar to a truncated cone nevertheless generatrix is far from a straight line, that can introduce sizeable errors to calculations. This difficulty can be avoided if approximate a considered body as a partially - conic surface, that is surface consisting of sequence of the truncated cones, continuing one another with some fracture. Such approximating can be as much as exact if we increase indefinitely the quantity of truncated cones, approximating given body.

Before consideration of mathematical models of elastomer shells' pressure based first of all on the mechanical characteristics of items, we shall accept as a working hypothesis, that the mechanical properties of elastomer items first of all are determined by a kind, quantity and way of location of elastomer threads, and in the second queue - rigidity of a ground interlacing.

As the second working hypothesis at calculation of pressure we shall accept, that interlay of elastomer threads in the ground interlacing results in conditionally one-dimensional deformation, and usage of elastomer threads results in two-dimensional deformation.

Creating model of an item by the way of thin shell, we do following assumptions:

- The material of a shell obeys to a Hooke's law;
- The deformation of a shell happens uniformly on a circle.

In work [4] the mathematical model of calculation of pressure of a textile shell was considered in case of one-dimensional deformation.

As a result of theoretical calculation the formula for definition of pressure in a shell depending on change of initial radius of a shell and length of a circle under operation of force P, with allowance for rigidity of a shell is obtained.

On this technique the experimental check of samples is carried out.

Let's consider a mathematical model in case of two-dimensional deformation.

Let's represent the method of calculation of pressure created by a shell, with allowance of real geometrical sizes of a leg and both physical and mechanical parameters of a shell, as a model at two-dimensional tension, the calculation of wich is made with the help of a finite element method [5].

This method requires following steps:

- The modeled body is divided into absolute (final) units and their nodes. Calculation is made in nodes, and the nodes during calculation are displaced.
- The force in each element of the unit is defined by displacement of node connection. It is derivation of a local matrix of viscosity.
- Compilation of algebraic equation system (global compilation of a matrix).
- Solution of a set of equations.
- Internal stress - definition of components in a condition of deformation.

Basing on the program Auto CAD, the real shape of a surface of a leg in three-dimension (Fig. 1) is figured. And the shell is shown as grid, divided in triangular finite elements, and their tops are connected among themselves.

Calculation of pressure created by an item (shell), needs the program of a finite element method, for example, the program ANSYS, which from the geometrical data obtained in Auto CAD, on input increments of units determines stresses and efforts arising in a shell.

For program solution of the given task it is still necessary to determine a number of physical and mechanical parameters of the material (shell). Thus, considering the shell as orthotropic, it was necessary to define following parameters:
E_1 - tension modulus;
E_2 - shear modulus;

G_{12} - shearing modulus; γ_{12} and γ_{21} - Poisson's constants.

These data were determined experimentally.

The elongation of the shell is determined on a dynamometer, under operation of force P. The values E_1 and E_2 were obtained using these data and substituting them in a design formula.

$$P/lh=E_{1;2}\,\Delta l_{1;2}/l_{1;2}$$

Shearing modulus G_{12} was determined experimentally too. The longitudinal edges of a sample were previously glued by a rigid material. Then the upper corner of a sample was consolidated in a support, and to the lower opposite corner freight (P = 0,5H) was hanged, thus a turn angle of a sample under the given load was fixed.
Outgoing from the formula:

$$G_{12}=E_{1;2}/2(1+\gamma_{12}) \qquad (7)$$

The Poisson's constants γ_{12} and γ_{21} were got.
The obtained outcomes are shown in table 1.

Outcomes of calculations.

Table 1.

E_1	E_2	G_{12}	γ_{12}	γ_{21}
0,612	0,302	0,064	3,8	1,37

Then these data were entered into the standard program ANSYS. As a result of calculations performed, this program obtained values of normal pressure on a surface of a leg, the distribution of which is shown in a fig. 4.

Conclusions:

The technique of calculation of pressure created by a shell in contact with a curvilinear surface of a body (for example leg) is determined.
The technique is based on simulation using a finite element method.

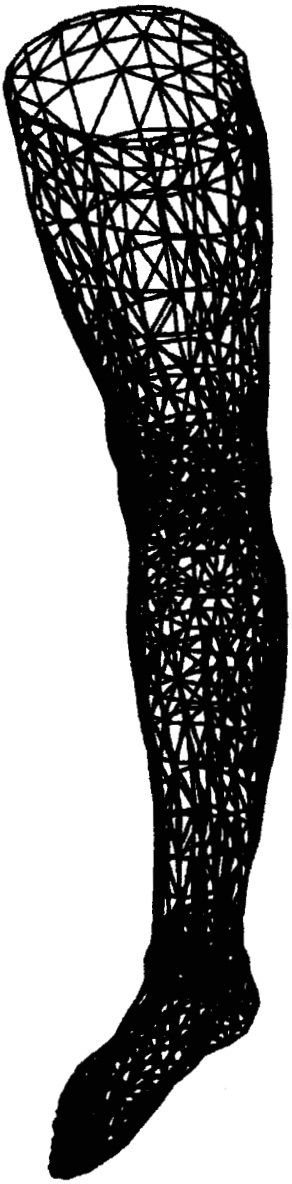

Fig. 3 . Surface shell of a leg.

Literature

1. Thora S. Ieteikumi medicīnisko pusgaro zeķu izgatavošanai. - R.:P.Stradiņa Republikāniskā klīniskā slimnīca, 05.03.97.

2. Писаренко Г.С., Агарев В.А., Квитка А.Л., Попков В.Г., Уманский Э.С. Сопротивление материалов. –К.: Голов.изд. "Вища школа", 1986, -775с.

3. Филатов В.Н. Упругие текстильные оболочки. –М.: Легпромбытиздат, 1987, -246с.

4. I.Ļašenko, B.Okss Medicīnska pielietojuma pusgarās zeķes spiediena aprēķināšana. –R.: Rīgas Tehniskā universitāte, UDK 677.075:613.4]:53.

5. Калинка Ю.А. Метод конечных элементов в сопротивлении материалов. –Р.: Рижский политехнический институт, 1985, -44с.

11. Twenty Years of New Development – What Clinical Benefit for the Patient?

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Introduction

In the past 20 years the development of new materials for dressings has been paralleled by an increasing desire to improve the general standards of care a patient with a wound receives. Currently emphasis is placed on providing pro-active rather than reactive care so that problems experienced by patients in the 1970's are seen as a thing of the past. The following three cases outline typical scenarios that may have confronted practitioners in the early 1970's. The same patients are reviewed in relation to the type of care they would receive in the 1990's.

Pressure Sores

Case Study 1: A 54-year-old single male paralysed below the waist with multiple pressure sores to buttocks and hips. He has had previous episodes of sores.

Care 1970's
Wound Care
Local
General Management
? Water bed
Sheepskin/rubber ring
'Back' round
Prevention
Assessment of patient skin

Care 1990's
Wound Care
Moist dressings
Growth factors
Plastic surgery
Treatment underlying infection
General Management
High tech mattress/beds
Prevention
Risk assessment
Prevention policies
Specialist nurses
Prevalence data

Case Study 2: A 28 year old self-employed carpenter, IDDM since 13 years of age, injury from masonry nail, abscess development 48 hours following injury.

Care 1970's	Care 1990's
Wound Care	**Wound Care**
Dry dressing/eusol/gauze	Growth factors/tissue engineering
Amputation	Debridement
Systemic antibiotics	**General Management**
General Management	Specialist multiprofessional clinics
Hospital clinic for DM control	Diabetic control
Prevention	Diabetes nurse specialist
Treatment of complication of presentation	**Prevention**
	Lowering amputation rate (St Vincent Declaration)
	Community/Diabetic clinics

Case Study 3: 78 year old widow, ulcer unknown aetiology right leg, third recurrence

Care 1970's	Care 1990's
Wound Care	**Wound Care**
Dry dressing/saline and gauze	Moist dressings
Crepe or elastocrepe bandage	Tissue engineering/growth factors
General Management	Compression bandaging
Keep legs dry	Care of surrounding skin
Occasional vascular assessment	**General Management**
Prevention	Vascular assessment for diagnosis
Accepted 'old' age problem	Referral to vascular surgeon
	Prevention
	Recognition of pre-disposing factors
	Leg ulcer clinics
	Health education – prevent recurrence

In the 1990s patients can expect an increased level of specialist input, equipment and treatment of the underlying causes of the wound problem.

Dressing Products

Undoubtedly dressings make a major contribution to the management of wounds. Correct assessment and diagnosis of wound aetiology, together with a broad

understanding of the properties and action of modern materials will facilitate healing and maximise patient comfort.

Wound dressings of today bear no resemblance to the basic supply of gauze and Gamgee used 20 years ago. The major change is attributed to the work of a Zoologist, George Winter (1927-1981). Winter's original experiment was published in 1962[1] and since that time the phrase "moist wound healing" has been used by manufacturers as one of the, if not **the**, most important feature of a modern wound dressing. This work was not intended to be generalised to a clinical setting only to observe changes in the covering, which influenced healing. However it heralded a revolutionary change in the approach taken by dressing manufacturers and clinicians alike.

A vapour-permeable, bacterial occlusive, self-adhesive polyurethane foam dressing was the first commercially available dressing to be produced. Now commonly referred to as semipermeable adhesive films, they were originally marketed as primary dressings. The most important feature of these dressings is their Moisture Vapour Transmission Rate (MVTR). The MVTR controls the passage of water vapour from underneath the dressing to the external environment. This prevents maceration and decreases the possibility of infection by preventing the accumulation of sweat and secretions[2] thus providing the patient with a more comfortable wound environment. Continued research since the 1970's has demonstrated that wound healing is a dynamic process and therefore the functions that are required of a dressing will change as the characteristics of the wound alter. In the 1990's successful wound management depends on a flexible approach to the selection and

use of products of the various dressings available. Without such knowledge dressing selection is likely to be arbitrary, and potentially ineffective and wasteful of both time and resources. The choice of dressing did not present a particular challenge 20 years ago, as it was limited to simple products. The extensive range of products now available can present a problem even though there is a plethora of information available to practitioners, research findings are not always conclusive and may not be implemented in practice[3-6].

The way in which dressings are chosen still remains a matter of ritual or haphazard choice in many areas of clinical practice. It would seem that fundamental problems could be attributed to interpersonal factors and the failure, still, of professionals to work together as a team[5]. This has particular implications when the use of products such as growth factors are indicated. Although there is considerable interest in the use of these substances, hospital and community budget holders may be reluctant to allow prescriptions of such expensive agents without strong clinical evidence of their efficacy.

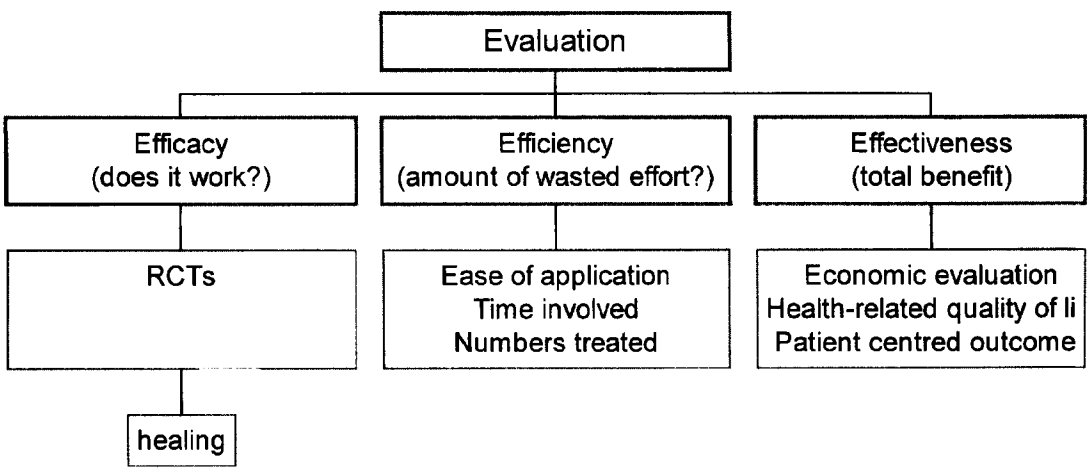
Specialist Nurses

The role of the Clinical Nurse Specialist in wound care can vary greatly but their main role has traditionally centred around pressure sore prevention and leg ulcer management. Because of the disparity in roles it is often difficult to evaluate how effective these specialists have been in improving the qualify of care a patient receives. Often they are accused of being protective of their specialist skills and knowledge in order to retain power[6,7] and are said to know 'more and more about less and less'[8].

What benefit for the patient?

It is very difficult to estimate whether the benefit to patients has increased over time. This is due to a range of issues, including changes in reporting of incidence and prevalence of wounds as well more accurate wound measurement methods and changes in evaluating outcomes. 'Outcome measures' is a relatively new concept that has developed steadily over the past 20 years. This area includes both patient centred outcomes (e.g., health-related quality of life {HrQOL} and health status) and outcomes of process (e.g., cost based evaluations). Traditional measures of clinical efficacy in wound-care have focused on speed of healing, including 'days to healing'. More recently, definitions of 'evaluation' have expanded to include a range of assessment objectives[9]. Figure 1 below summarises the key components to be included in the total evaluation of any given intervention or service provision. Each of these elements will be outlined below.

Figure 1: Key elements of evaluation



Measures of efficacy

The efficacy of a treatment / service is usually measured via statistical concepts. Efficacy studies usually report proportions of patients improved or in remission after defined periods of time. If death is an issue then the results are presented as survival curves, or proportions still alive after a defined period. Efficacy is usually tested through randomised clinical trials (RCTs), which are considered the 'gold standard' method for collecting such data.

The advantages and disadvantages of using RCTs have been outlined in the literature[10,11], although there are some issues that are especially pertinent to wound-care. For example, the use of a homogenous group in wound care caused problems in terms of:

- aetiology, size and duration of the wound,
- the presence of infection, pain, exudate or odour
- the concordance of the patient with treatment instructions.

The endpoints used in RCTs in woundcare also vary across studies and include:

- Percentage of patients healed
- Time to complete healing
- Percentage change in area
- Absolute change in area
- Total area healed
- Mean adjusted rate
- Surrogate endpoints (e.g., area debrided).

This range of endpoints can make it difficult to compare the efficacy of different interventions.

Measures of Efficiency

Efficiency refers to the organisational aspects of health care, and is often reported via such measures as number of patients treated for a given number of outpatient sessions. There is, however, a close relationship between efficiency and efficacy - if the treatment is not efficacious, patients may need to return more frequently fir further treatment.

The majority of studies in wound-care that focus on efficiency, are relatively small-scale product evaluations. However, there are projects, which have focused on service delivery and emphasised efficiency as well as efficacy[12,13]. Long term follow-up studies, which are expensive and time consuming, are needed to examine the relationship between efficacy and efficiency.

Measures of Effectiveness

This section refers to a broad range of economic and patient centred assessments. Economic evaluation assesses the value for money from different interventions or in different services, and includes a range of methods:

1) Cost- effectiveness analysis

This method of analysis is often used when interventions have a single and readily measurable outcome that can be compared in terms of cost per unit of outcome. The aim of cost-effectiveness analysis is to find the cheapest form of delivery for the same impact on a population[14].

2) Cost-benefit analysis

Cost-benefit analysis measures all the inputs and outputs of treatment and care in monetary value. One of the controversies of this method is the translation of all costs

and benefits into monetary values, one method of assessing monetary value is based on an individual's 'willingness to pay' for a given benefit.

3) Cost-Utility Analysis

Cost-utility analysis measures outcomes in utility measures (usually Quality Adjusted Life Years or QALYs) which combine mortality and morbidity (i.e., combining quantity and quality of life). Quality adjustment consists of having people assign weights to life years in different health states on a scale where 'dead' scores 'zero' and 'healthy' scores 'one'.

4) Modelling Techniques

In some diseases or disorders patients move repeatedly between health states (e.g., healed -v- not healed, infected -v- not-infected, superficial infection -v- deep infection). In such cases modelling can be used to estimate the economic impact of different health states. For example, Eckman et al (1995)[15] used a Markov State Transition Model to look at cost-effectiveness in foot infections in diabetic patients. As in other methods given above, Health Related Quality of Life can be used as part of this process to weight the outcomes.

Financial studies of wound-care have only relatively recently started to appear in the literature, although some review papers have been published[16]. Caution has been expressed about cost-effectiveness studies in terms of required complexity of design and comparability of findings[17-19]. Most difficulties focus on the nature of the costs to be included in cost-effectiveness studies [e.g., should these be only direct costs (e.g., cost of dressing etc.) or should indirect costs be included (e.g., travelling time for dressing changes etc.)?], rather than issues related to methodology.

Patient centred outcomes include health-related quality of life, health status, patient satisfaction and patient perspective on new technologies. Implicit in the concept of patient centred outcomes is a move away from traditional measures of the medical process (e.g., glucose level) towards those aspects of care that have direct relevance to the patient.

In health care, a restricted use of the term 'Quality of life' is employed to mean those aspects of life quality that relate to health (Health-related quality of life)[20]. HrQOL trials can help to improve the quality of a given patient's treatment or outcome, by differentiating between therapies with marginal differences in mortality or morbidity - or by comparing treatment modalities, e.g., surgery -v- medicine. In addition, HrQOL studies can help us to understand the burden of specific diseases or conditions on everyday functioning and well-being. HrQOL also has policy and commercial implications such that planners need to be aware of the HrQOL implications of treatments / services when allocating resources, whilst companies may focus their product development to focus on HrQOL improvements.

There has been a growing awareness of HrQOL in wound care over the past 5 years, and there are a number of review papers which outline the issue of HrQOL in patients with chronic wounds [21,22]. Such reviews address the issues of generic compared with condition-specific tools for collecting data, as well as the issues related to the use of profiles or indices in presenting such data.

Patient satisfaction is closely related to HrQOL, although it focuses on different aspects of both process and outcome. Measures of satisfaction are relatively new in

wound-care, and there are a range of methodological difficulties which have to be overcome in order to ensure that patients are not simply reporting favourable levels of satisfaction in order to avoid upsetting those providing their health care[23]. The perspective of the patient on the introduction of a new or innovative technology, or new treatment option can result in important issues being addressed prior to the implementation of the new development on a wide scale. Such studies[24] can give an in-depth understanding of the expectations and needs of the individual in terms of information and/or support required to adapt to the treatment option proposed.

Conclusion

All the factors outlined above have financial implications for the NHS. It was estimated in 1992 that wound care costs to the NHS were around £950 million[25]. Changes in demographics over the next 40-50 years will see an increase in the UK population in the over 65 year group who will form 20.5% of the population[26]. Incidence of pressure sores increases with the older hospitalised patient[27,28] and evaluation of pressure relieving equipment is essential for economic resource allocation. The incidence of leg ulceration also increases with age and with the majority of these patients cared for in the community the establishment of community[29] leg ulcer clinics have been considered to be economically beneficial to both patient and NHS[12].

Total evaluation of any treatment or service provision is the only way in which all aspects of the process and outcome of an intervention can be fully assessed. In an economic climate of limited resources and increased demand for health care, policy planners and budget holders will require convincing in-depth data that address a range of issues in addition to the traditional outcome of medical efficacy. In wound care we

may not be able to clearly state the extent of improvement in clinical care and outcomes, as there is so little baseline data from 20 years ago. However, in order to ensure that future interventions are demonstrably effective, we must adopt a philosophy of total evaluation.

References:

1. Winter GD. *Formation of the scars and the rate of epithelisation of superficial wounds in the skin of the young domestic pig.* Nature 1962, **193**: 293-294.
2. Thomas S. *Vapour–permeable film dressings.* Journal of Wound Care 1996, **5:6**; 271-274.
3. Draper J. *Making the dressing fit the wound.* Nursing Times 1985, **81:41**, 32-35.
4. Irvine A and Black C. *Pressure sore diabetes.* Nursing Times 1990, **86:38**, 74-78.
5. Flanagan M. *Variables influencing nurses selection of wound dressings.* Journal of Wound Care 1992, **1:1;** 33-43.
6. Luken KA and Kenvick M. *An exploratory study of the sources of influence on the clinical decisions of community nurses.* J Advanced Nursing 1992, **17**: 457-466.
7. Chapman C. *The paradox of nursing.* J of Advanced Nursing **8: 269-272.**
8. Wade B and Moyer A. *An evaluation of clinical nurse specialists – Implications for education and the organisation of care.* Senior Nurse 1989, **9:9,** 11-16.
9. St.Leger AS, Schnieden H & Walsworth-Bell JP. *Evaluating Health Services' Effectiveness.* 1992 Milton Keynes: O.U.P.
10. Coleridge Smith PD Investigation of patients with venous ulceration. *Phlebology* 1992, **1:** 17 - 21

11. Cullum N. Evaluation of treatments for wounds in clinical trials. *J Wound Care* 1996, **5** (1): 8-9

12. Moffat CJ, Franks PJ, Oldroyd M et al Community clinics and impact on healing. *BM J* 1992, **305**: 1389-92

13. Morrell CJ, Walters SJ, Dixon S, Collins KA, Brereton LML, Peters J, Brooker CGD. Cost-effectiveness of community leg ulcer clinics: randomised controlled trial. *BMJ*, 1998, **318**: 1487 - 1491

14. Towse A. Introduction to cost-effectiveness, theory and practice. *Cost Effectiveness of Wound Treatments*, 1994 Proceedings of a Symposium 4th Annual Meeting of the European Tissue Repair Society.

15. Eckman MH, Greenfield S, Mackey WC, Wong JB, Kaplan S, Sullivan L, Dukes K and Pauker SG *Foot Infections in Diabetic Patients: Decision and cost-effectiveness analyses*. JAMA,1995, **273** (9) : 712 - 720

16. Ragnarson-Tennvall G and Apelquist J Cost-effective management of diabetic fool ulcers: a review. *Pharmacoeconomics* 1997 Jul **12**(1): 42 - 53.

17. Bale S, Jones V, Banks V, Harding, KG Problems and pitfalls of doing cost-effectiveness studies *Proceedings of 2nd Congress of Advances in Wound Healing*,1992 p.45 - 47

18. Brooks R, Semlyen A. Economic appraisal in pressure sore management. *J Wound Care* 1997, **6** (10): 491 - 494

19. Drummond M. and Jefferson T Guidelines for authors and peer reviewers of economic submissions to the BMJ. *BMJ*,1996, **313**: 275 - 283

20. Price P. Defining and measuring Quality of Life. *J.Wound Care*, 1996 **5**(3): 142 - 143.

21. Price P. Quality of life assessment in wound management. In A.Suggett, G.Cherry, R.Mani and W. Eaglstein (eds) *Evidence-Based Woundcare.* 1998, International Congress Symposium 227: Royal Society of Medicine.

22. Franks PJ, Moffatt CJ. Quality of life issues in patients with chronic wounds. *Wounds : A Compendium of Clinical research and Practice.* 1998 10 Supp E 1E – 9E.

23. Collins K, Morrell J, Peters J, Walters S, Brooker C, Brereton L. Problems associated with patient satisfaction surveys. *Brit Journal of Comm Health Nursing,* 1997: **2** (3): 156 - 163

24. Price, PE and Harding, KG The patient perspective on new therapies (Dermagraft). Proceedings of 7th *European Conference of Advances in Wound Management*:1998, 84 - 86

25. Cockbill SME. *Wound Care problems in the community.* In Harding KG, Leaper DL, Tuman TD (eds). Proceedings of *First European Conference on Advances in Wound Management,* 1991, London, Macmillan.

26. *Office Health Economics*. Compendium of Health Care Statistics 1991, London OHE.

27. David G, Chapman ET et al. *An investigation into the current methods used in nursing for the care of patients with established pressure sores.* Harrow Nursing Practice Unit 1983.

28. Allman RM. *Epidemiology of pressure sores in different populations.* Decubitus 1989, **2:2,** 30-33.

29. Callum M, Ruckley C, Harper D et al. *Chronic leg ulceration of the leg – extent of the problem and provision of care.* Br Med J 1985, **290: 6458;** 1855-1856.

Session 3: Healthcare and hygiene

12. Development of a Versatile Antimicrobial Finish for Textile Materials for Healthcare and Hygiene Applications

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SUMMARY

This paper discusses the treatment of textile materials with a synergistic system of chemical formulation to render them antimicrobial. The recipe comprises of inorganic chemicals known to be non-toxic to human beings. The treated materials possess excellent bactericidal activity against various Gram positive and Gram negative non-spore bearing and spore bearing bacteria and the full effect has been observed upto 50 launderings. Hospital field trials using the treated bed linen, patients' gowns and staff aprons in post-operative, gynaecology and labour wards further substantiated the antibacterial effect and the durability of the finish and the users did not experience any discomfort in using the finished materials. The dermatological patch test carried out on patients and medical staff revealed that the treated materials are safe to use and do not produce any dermatological problems such as irritation or allergy. The treatment reduces the chances of severity and propagation of ailments conveyed through fabrics and garments. It does not alter the physical properties and of course increases the tear strength and wear life of the textile materials. Besides, it protects the cellulosic fibres from microbial attack on storage. The fastness properties of the dyed items are unaffected by this treatment. In addition to healthcare and hygiene applications, the formulation can also be used as an effective antimildew agent in protecting the growth of mildew in sizing recipes and is an alternative to banned pentachlorophenol. It can also serve as a good antifungal agent against cloth damage and plant pathogenic fungi.

INTRODUCTION

Medical textiles account for a huge market due to widespread need not only in hospitals, hygiene and healthcare sectors but also in hotels and other environments where hygiene is required. There has been a sharp increase in the use of natural as well as synthetic fibres in producing various medical products. It is forecasted[1] that the annual growth of medical textile products is likely to be around 10% during the year 1999-2000.

It is known that microorganisms create and aggravate problems in hospitals and other environments by transmitting diseases and infections through clothing, bedding etc. The axillae and perineal regions of the body are more susceptible to microbial growth that leads to undesirable body odour. It is reported[2] that polyamide fibres retain more odour causing microorganisms than natural fibres. Polyester and other synthetic fibres are also prone to the growth of pathogenic microorganisms. Besides, microorganisms deteriorate cellulosic fibres and reduce the wear life of the materials[3]. They adhere to the surface of the fibres, gradually corrode inwards layer by layer disintegrating the primary and secondary walls of the fibres causing considerable damage[4]. It may be noted that bacteria are usually active at pH 7.0-8.0 and fungi at 4.0-6.5. Fungal growth on textile materials is more rapid at RH greater than 80%[2]. With repeated launderings the bacterial propagation increases by about 30% more colonies on 15 times laundered fabric than the unlaundered ones[5]. Similarly a large number of fungi have been isolated on exposed cotton textiles[6]. Thus microorganisms exist in abundant

quantities on textile materials and propagate diseases and infections and also cause damage to fibres under normal usage and storage conditions. In order to combat these adversities, it is highly desirable to impart antibacterial, antifungal and mildew resistance properties to textile materials by imbuing antimicrobial agents into the fibres or by preventing direct contact between the microorganisms and the fabric through coating.

With a view to develop such textile materials, considerable research has been carried out by making use of organic and inorganic compounds, antibiotics, heterocyclics, quaternary ammonium compounds and so on. Some recent developments in antibacterial products include a process involving the preparation of antibacterial resins containing phenol derivatives[7]. The resins exhibited higher antibacterial activity against *escherichia coli* and *staphylococcus aureus.* Beliakova *et al*[8] discussed the process for preparing an antibacterial formulation by reaction of carboxymethyl starch with trimethylolated melamine in the presence or absence of cupric ions to render cotton fabric antibacterial. Fabrics made from viscose fibres containing polysilicic acid (Visil®) and aluminium silicate (Visil AP®) have been given urea peroxide treatment to make them antibacterial as well as deodorant[9]. The cellulose has been modified chemically with biocides accompanied by redox reaction to achieve durable and regenerable antibacterial activity on cotton and other cellulosic fabrics[10]. The finish poly(hexamethylene biguanide hydrochloride) (Reputex 20®) imparts antimicrobial property to cotton and cotton blended materials that is effective against a broad spectrum of bacteria, fungi and yeasts and also durable to 50 launderings[11-12]. Vigo[13] studied the antimicrobial effect of polyols on cotton fabrics and found that crosslinked polyols suppressed the growth of microbes as well as odour. A formulation that is hydrolytically stable at ambient temperature for at least two months and thermally stable below 300°C has been prepared by making use of magnesium hydroperoxyacetate and magnesium dihydroperoxide to render cellulosics, chemical fibres and their blends bactericidal up to 50 launderings[14]. Chitosan treatment on cotton fabrics imparts antibacterial activity against *staphylococcus aureus* but the effect decreases on subsequent launderings[15]. It is to be mentioned that synthetic fabrics can also be made antimicrobial by treating them with antimicrobial agents[16-20].

In addition to imparting antibacterial activity to cotton and other cellulosic materials, research has also been carried out to protect them from fungus and mildew attack. The fungi *aspergillus niger* and *chaetominum globosum* normally cause the growth of mildew on textiles especially under high humid condition that leads to deterioration, staining, and discolouration of fabrics[21-22]. Studies proved that octhilinone controls the growth of mildew on cotton fabrics[23] and chlorine bleach removes the stain produced by mildew[24].

MATERIALS AND METHODS

Materials

100% cotton plain weave fabric after scouring and bleaching but before finishing was used. For the antimicrobial finish, a synergistic system of chemical formulation (10% aqueous) consisting of a metal salt of monocarboxylic acid, a carbamic derivative, a chelating agent, and a boron compound was prepared and the dosage was optimised consequent to several modifications in recipe composition. The formulation was mixed with an aqueous solution containing a dimethylene siloxane derivative and an alkane polymer when finishing the fabric.

Antimicrobial treatment

The fabric samples were impregnated with the aforementioned recipe, padded to a wet pickup of about 70%, dried at 80°C for 10 minutes and cured at 150°C for 5 minutes followed by water wash to remove any residual chemicals.

Testing

The following bacteria and fungi were incorporated to test the antimicrobial activity of both the formulation and the fabric samples.

Gram-positive bacteria
Staphylococcus aureus or pyogens
Staphylococcus epidermidis
Corynebacterium diphtheroides

Gram-negative bacteria
Escherichia coli
Klebsiella pneumoniae
Proteus vulgaris
Pseudomonas pyocynans
Salmonella typhi
Vibrio cholerae

Cloth damaging fungi
Aspergillus niger
Aspergillus fumigatus
Trichoderma viride
Curvularia lunata
Penicillium species

Crop damaging fungi
Fusarium species
Rhizoctonia solani
Sclerotium rolfsii

The antimicrobial activity of the formulation as well as the treated and untreated samples was evaluated both qualitatively and quantitatively using the standard test methods such as Agar plate method[25], AATCC method[26] and Poison food technique[27]. To test the laundering durability, the samples were washed in a washing machine according to AATCC procedure[28]. SEM (JEOL-T 330A-368) observations were carried out on the samples after coating with Au-Pd in a vacuum fine coat ion sputter (JFC-1100). Tensile and tear strengths and various fastness properties were assessed by conventional testing methods.

RESULTS AND DISCUSSION

Antibacterial activity

Laboratory studies

A qualitative analysis was initially carried out by inoculating different bacteria in petri dishes containing various cultural media (blood agar, nutrient agar and MacConkey agar) with and without antimicrobial formulation and treated as well as untreated cloth samples. The bacteria were grown under ideal conditions. It is observed that there is no bacterial growth in the petri dish containing formulation whereas tremendous growth in the control dish. Similarly a clear bacteria free ring zone around the treated sample is noticed in the agar medium and, on the other hand the bacteria are grown heavily on the untreated sample. The results are further substantiated by quantitative analysis. Table 1 shows the antibacterial activity of treated and untreated samples against Gram positive and Gram negative spore bearing and non-spore bearing bacteria.

It is seen that the treated samples exhibited over 97% reduction in the number of colonies of all types of bacteria except *pseudomonas pyocynans* where the reduction is 75%. This indicates that the treated fabric has got excellent antibacterial activity against the major disease causing including spore bearing bacteria. It may be mentioned that the eradication of spore bearing bacteria is not easy and the Gram positive *staphylococcus aureus* is resistance to most antibiotic substances[29]. A complete inhibition of the growth of undesirable perspiration odour causing bacteria (*staphylococcus epidermidis* and *corynebacterium diphtheroides*) was also observed in the treated samples.

Table 1. Antibacterial Activity of Treated and Untreated Fabric Samples

Bacteria	Quantitative Evaluation (Colony/ml)		Reduction (%)
	Untreated	Treated	
Non-spore-bearing bacteria			
Staphylococcus aureus	93,000	No growth	100
Staphylococcus epidermidis	46,000	No growth	100
Escherichia coli	78,000	No growth	100
Klebsiella pneumoniae	90,000	1,000	98.9
Proteus vulgaris	30,000	3,000	90.0
Pseudomonas pyocynans	57,000	14,000	75.4
Corynebacterium diphtheroides			
Strain No.1	54,000	No growth	100
Strain No.2	68,000	No growth	100
Spore-bearing bacteria			
Bacillus subtilis group			
Strain No.1	72,000	2,000	97.2
Strain No.2	68,000	1,000	98.5
Strain No.3	48,000	No growth	100
Strain No.4	87,000	1,000	98.9
Strain No.5	73,000	2,000	97.3
Strain No.6	55,000	No growth	100
Strain No.7	70,000	No growth	100

Durability of finished samples

In order to ascertain the durability of antimicrobial finish, the samples were washed and the effect was analysed after 5,10, 25 and 50 use-wash-use cycles. Excellent retention of bactericidal property was observed even after 50 washes (Table 2).

Hospital field trials

Hospital trials were conducted to check the bulk applicability and acceptability of the treated fabrics. Initially, the 'Patch Test' was performed on 100 willing patients and medical staff of different age groups to check the dermatological effect of the treated cloth on skin. The treated samples (2.5 X 2.5 cm) were affixed on the forearm of the persons using microplaster and inspected the contact area of the skin after about 72 hours. The test and also the counselling with the users revealed that the treated sample didn't produce any allergy, irritation and unpleasant odour to human beings.

Table 2. Antibacterial Activity of 50 Times Washed Samples-Laboratory Trial

Bacteria	Quantitative Evaluation (Colony/ml)		Reduction (%)
	Untreated	Treated	
Staphylococcus pyogens	145,000	No growth	100
Escherichia coli	142,000	No growth	100
Klebsiella pneumoniae	160,000	No growth	100
Proteus vulgaris	140,000	3,000	97.9
Salmonella typhi	120,000	2,000	98.3
Vibrio cholerae	152,000	No growth	100
Pseudomonas pyocynans	120,000	560,00	53.3

Bed linens, patients' gowns and staff aprons were tailored using both the treated and untreated fabrics and were put to use in post-operative, gynaecology and labour wards of a reputed hospital. The presence of bacteria on treated and untreated items was tested after several use-wash-use cycles. It is observed from the results after 50 cycles (Table 3) that while the untreated samples are rich in some types of bacteria, the treated ones are almost devoid of them. It may be mentioned that the users didn't experience any discomfort like skin irritation, disagreeable odour and unpleasantness during the trial.

Antifungal activity

The formulation and the treated samples were tested for their antifungal activity against various cloth damaging fungi by Poison food technique and Agar plate method respectively. The fungal strains were inoculated in the petri dishes containing the media with and without the formulation and the extent of growth at different time was measured. It is noted (Table 4) that the control petri dish is fully covered with fungi in 96 hours but the fungal propagation is completely arrested by the formulation even after 120 hours of incubation. The effect on the treated fabric was also confirmed by absence of fungi while the control fabric showed abundant growth.

The efficacy of the formulation against crop damaging fungi was also tested for interest. It is seen (Table 5) that the fungal spread is inhibited by the formulation even after 192 hours.

Properties of Treated Fabrics

The physical and fastness properties are depicted in Tables 6 and 7 respectively. While the tensile strength of treated sample is unaltered, the tear strength increases by 26% in warp and by 6% in weft directions respectively. The fastness properties of the dyed samples are unaffected by the treatment.

SEM studies were carried out on samples stored for several months and also induced by bacteria and fungi. The examination revealed that while the untreated samples showed disruption of fibres leading to loose ends, clusters and spots, the treated samples possessed marked improvement in maintenance of fibre positions and fabric structure. The SEM micrographs of control and treated samples on storage are depicted in Figures 1 and 2 respectively.

Table 3. Antibacterial Activity of 50 times Washed Samples-Hospital Trial

Wards	Organisms isolated from aprons, gowns & linens	Observation (Growth of organisms)	
		Untreated	Treated
Post operative	*Escherichia coli*	Moderate	Nil
	Klebsiella aerosens	Moderate	Nil
	Staphylococcus pyogens	Heavy	Insignificant
Gynaecology	*Escherichia coli*	Moderate	Nil
	Staphylococcus pyogens	Moderate	Nil
	Pseudomonas pyocynans	Moderate	Nil
Labour	*Escherichia coli*	Heavy	Heavy
	Klebsiella pneumoniae	Heavy	Heavy
	Staphylococcus pyogens	Heavy	Insignificant

Table 4. Effect of Formulation on the Growth of Cloth Damaging Fungi

Fungi	Radial growth (mm) after					
	18 hrs	24 hrs	48 hrs	72 hrs	96 hrs	120 hrs
Aspergillus niger						
Untreated	5.3	6.3	20.0	32.3	45.0*	-
Treated	4.0	4.0	4.0	4.0	4.0	4.0
Aspergil. fumigatus						
Untreated	5.0	7.0	19.6	35.6	45.0*	-
Treated	4.0	4.0	4.0	4.0	4.0	4.0
Trichoderme viride						
Untreated	5.3	7.6	23.0	45.0*	-	-
Treated	4.0	4.3	4.3	4.3	4.3	4.3
Curvularia lunata						
Untreated	5.0	7.0	18.0	27.0	39.0	45.0*
Treated	4.0	4.0	4.0	4.0	4.0	4.0
Penicillium sp.						
Untreated	4.6	5.6	9.6	22.6	36.6	45.0*
Treated	4.0	4.0	4.0	4.0	4.0	4.0

Note: Radius of the inoculated fungal petri dish is 4.0 mm.
Asterisk indicates that fungus covered the entire petri dish.

Table 5. Effect of Formulation on the Growth of Crop Damaging Fungi

Fungi	Radial growth (mm) after								
	18 hrs	24 hrs	48 hrs	72 hrs	96 hrs	120 hrs	144 hrs	148 hrs	192 hrs
Fusarium sp.									
Untreated	4.6	7.6	19.6	30.0	41.6	45.0*	-	-	-
Treated	4.0	4.0	4.0	5.3	6.6	8.0	9.3	10.0	10.0
Rizoct.solani									
Untreated	5.0	11.6	34.3	45.0*	-	-	-	-	-
Treated	4.0	4.0	5.3	6.3	8.0	9.3	11.0	11.0	11.0
Sclero.rolfsii									
Untreated	5.3	10.6	30.3	45.0*	-	-	-	-	-
Treated	4.0	4.0	5.6	6.3	8.3	10.3	11.3	11.3	11.3

Note: Radius of the inoculated fungal petri dish is 4.0 mm.
Asterisk indicates that fungus covered the entire petri dish.

Table 6. Strength Properties of Fabrics

Particulars	Tensile Strength				Tear Strength			
	Warp (kg)	Difference (%)	Weft (kg)	Difference (%)	Warp (gmf)	Difference (%)	Weft (gmf)	Difference (%)
Untreated	37.6	-	32.3	-	1504	-	1485	-
Treated	38.0	+1.1	31.6	+2.2	1894	+25.9	1574	+6.0

Table 7. Fastness Properties of Fabrics

Particulars	Washing		Acidic Perspiration		Alkaline Perspiration		Rubbing		Light
	Effect	Staining	Effect	Staining	Effect	Staining	Dry	Wet	
Untreated	4-5	4-5	4-5	4-5	4	4-5	3	2	6
Treated	4	4-5	4-5	4-5	4	4-5	3-4	3	6

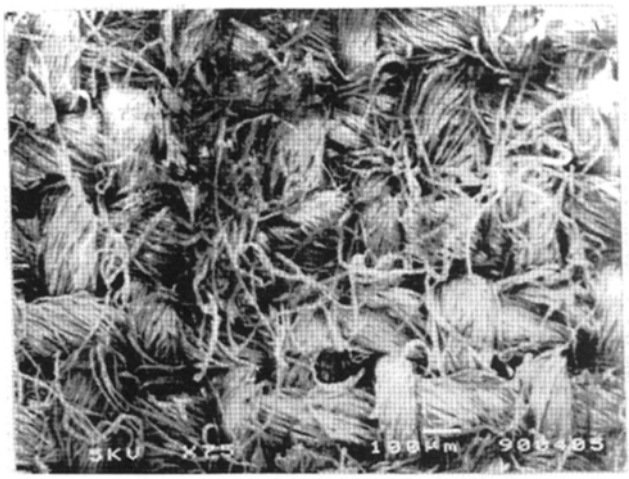

Figure 1. Untreated on Storage

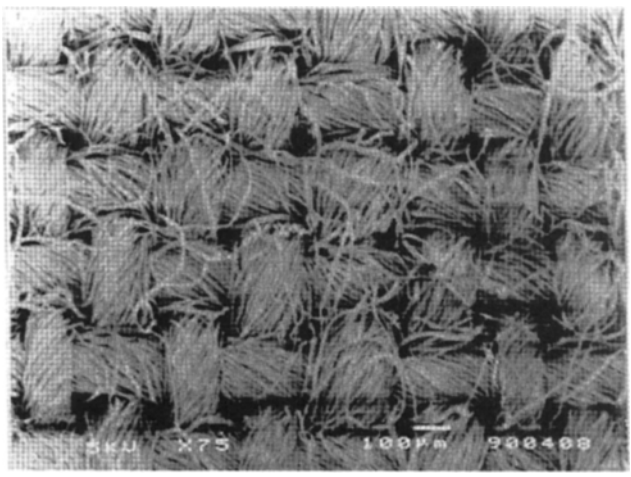

Figure 2. Treated on Storage

REFERENCES

1 A J Rigby, S C Anand and A R Horrocks, 'Textile materials for medical and healthcare applications', *J Text Inst*, 1997 **88** 83-93.

2 T L Vigo, *Textile Processing and Properties: Preparation, Dyeing, Finishing and Performance,* London, Elsevier, 1994.

3 N Seventekin and O Ucarci, 'Damage caused by microorganisms to cotton fabrics,' *J Text Inst*, 1993 **84** 304-313.

4 R G H Siu, *Microbial Decomposition of Cellulose*, New York, Reinhold, 1951.

5 C Barnes and J Warden, 'Microbial degradation: fibre damage from *Staphylococcus aureus*', *Text Chem Col,* 1971 **3** 52-56.

6 M Lewin and S B Sello, *Functional Finishes (Part A)*, New York, Marcel Dekker, 1983.

7 Y Nonaka, Y Uemura, K Ohse, K Jyono and S Kurihara, 'Preparation of resin coating phenol derivatives from chloromethylstyrene-tetraethyleneglycol dimethacrylate copolymer beads and antibacterial activity of resins', *J Appl Poly Sci*, 1997 **66** 1621-1630.

8 M K Beliakova and A Hebeish, 'A novel approach for preparation of antibacterial cotton fabrics', *Am Dyest Rep*, 1998 **87** 46-49.

9 Anon, Fibrous structure containing urea peroxide, *Medical Textiles*, 1998 **10** 3.

10 G Sun and X Xu, 'Durable and regenerable antibacterial cellulosic materials', *Am Chem Soci Abst*, 1997 Part 1 CELL 047.

11 J D Payne and D W Kudner, 'A new durable antimicrobial finish for cotton textiles', *Am Dyest Rep*, 1996 **85** 26-30.

12 J D Payne, D W Kudner J A Pierce and S K Lee, 'A new use of polymeric biguanide as a antimicrobial agent on cellulosics', INDA-TEC 96: *Book of Papers: International Nonwovens Conference*, 1996.

13 T L Vigo, 'Antimicrobial activity of cotton fabrics containing crosslinked polyols', *Proceedings of the Beltwide Production Conference*, 1993.

14 T L Vigo and G F Danna, 'Magnesium hydroperoxyacetate (MHPA) and magnesium dihydroperoxide (MDHP): new antibacterial agents for fibrous substrates', *Am Chem Soc Abst*, 1996 Part 1 CELL 090.

15 S Lee, J S Cho and G Cho, 'Antimicrobial and blood repellent finish for cotton and nonwoven fabrics based on chitosan and fluoropolymers', *Text Res J*, 1999 **69** 104-112.

16 J Buchenska, 'Pan fibres with antibacterial properties', *Fib & Text in Eastern Europe*, 1996 **4** 53-59.

17 J Buchenska, 'Antibacterial polyamide fibres', *Fib & Text in Eastern Europe*, 1996 **4** 80-84.

18 T Kawata, 'First permanently antibacterial and deodorant fibres', *Chem Fibr Int,* 1998 **48** 38-43.

19 Zh A Zgibneva, 'Study of the possibility of preparing polyacrylonitrile fibres with antifungal action', *Mater Resp Konf Tekst Khim*, 1974 **3** 24-25.

20 Anon, 'Polynosic fibre with antibacterial properties', *Medical Textiles*, 1992 **7** 1.

21 A J Turner, 'Microorganisms found on mildewed fabric-a new study reveals organisms to watch in preventing mildew growth', *Text Rental,* 1989 **72** 82-88.

22 T Andrasic, 'Handling mildew stains', *IFI Fabricare News*, 1993 **22** 13.

23 J A Meeks and D E Greenley, 'Prevent mildew damage on cotton fabrics', *Text Rental,* 1988 **71** 68-70.

24 B L Barnes, C E Blaco and K McLaren, 'Win the war against mildew', *Text Rental,* 1997 **80** 136-138.

25 AATCC Manual, Test Method-30, 1979, *Antibacterial Activity of Fabrics, Detection of: Agar Plate Method*, North Carolina, 1979.

26 AATCC Manual, Test Method-100, 1981, *Antibacterial Finishes on Fabrics, Evaluation of*, North Carolina, 1986.

27 B N Dhawan and R C Simal, *The Use of Pharmacological Techniques for the Evaluation of Natural Products,* UNESCO, India, 1984.

28 AATCC Manual, Test Method-124, 1984, *Appearance of Durable Press Fabrics after Repeated Home Launderings*, North Carolina, 1986.

29 Y Sakagami, 'The present situation of the antibacterial activity of the processed specimen clothes against methicillin resistant *staphylococcus aureus*', *J Soc Fibre Sci Technol*, 1995 **51** 256-26.

13. Air Permeability and Porosity Evaluation of Antiallergical Bed Linen

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1. INTRODUCTION

It is well known that one of main problems dealing with medical textiles used in hospitals is protection against particles causing illness. One solution is to use so called clean room textiles acting as a barrier protecting humans against surrounded atmosphere or vice versa These special medical textiles are mainly used for special clothing. It was shown, that in the clean rooms the pollution has to be below 100 CFU/ m^3 (CFU means colony forming units).

The clean room textiles are produced in the limited range of. porosity and air permeability. These textiles have often very unsatisfactory comfort.

Generally, clean room textiles have to satisfy to the following requirements:

- protect the atmosphere against particles emitted from human body (particle barrier)
- protect the atmosphere against particles evolved from clothing
- protect the human body against dust particles (carriers of microorganisms) from atmosphere.

In this paper the porosities calculated from fabric geometry and air permeabilities of typical clean room textiles of Czech production are measured. The variation of air permeability is described by the analysis based on the coefficient of variation and analysis of variance. The main aim is to evaluate the air permeability uniformity in the warp and weft directions.

2. EVALUATION OF FABRIC POROSITY

There exist three basic techniques for characterization of the idealized fabric porosity P_I from some construction parameters of weaves[3]. Classical parameters are sett (texture) of weft D_C [1/m], sett of warp D_M [1/m], fineness of weft yarn T_C [tex], fineness of warp yarn T_M [tex], planar weight of weave W_P [g m^{-2}], density of fibers ρ_F [kg m^{-3}] and thickness of fabric t_W [m].

A. **Density based porosity** P_W is computed from the equation

$$P_W = \rho_W / \rho_F \tag{1}$$

where ρ_W is volumetric density defined by the relation

$$\rho_W = \frac{m_V}{v_V} = \frac{W_P}{t_W^2} \tag{2}$$

where m_V [g m^{-3}] is volume weight of fabrics equal to the W_P / t_W and v_V [m^3] is volume

of fabrics having surface of 1 m^2.

From the measured planar weight W_P, fabric thickness t_W and known density of fibers is the simple to compute the „real" porosity

$$P_W = \frac{W_P}{\rho_F \, t_W^{\,2}} \tag{3}$$

B. **Porosity based on the hydraulic pore definition** P_{HW} is defined as

$$P_{HW} = 1 - \frac{\text{volume covered by yarns}}{\text{whole accessible volume}} = \frac{v_Y}{v_V} = 1 - \frac{v_Y}{t_W} \tag{4}$$

The V_Y is equal to the sums of volume of weft yarns SU_C and warp yarns SU_M

$$V_Y = SU_C + SU_D \tag{5}$$

where

$$SU_C = D_C \, v_{1C} \tag{6}$$

$$SU_D = D_M \, v_{1M} \tag{7}$$

Here the v_{1C} and v_{1M} are volumes of weft and warp yarn in the 1 m portion of fabrics

$$v_{1C} = l_C \, \pi \, d_C^{\,2} / 4 = l_C \frac{T_C}{10^3 \rho_C} \tag{8}$$

for v_{1M} the indexes C are replaced by the indexes M. For the case of $\rho_{FC} = \rho_{FM} = \rho_F$ can be porosity P_{HW} expressed by the relation

$$P_{HW} = 1 - \frac{1.1 * 10^{-6}}{\rho_F \, t_M} \left[D_C T_C + D_M T_M \right] \tag{9}$$

C. **Porosity based on the cover factor** P_{CF} is derived from the pure geometry of yarns projection. Classical Pierce definition of CF is computed from the idealized projection of fabric

$$CF = D_C d_C + D_M d_M - d_C d_M D_C D_M \tag{10}$$

Corresponding porosity is defined by relation

$$P_{CF} = 1 - CF \tag{11}$$

For the **idealized circular yarn** with the same packing density is simple to compute diameters from relation

$$d_C = \frac{2\sqrt{T_C}}{\sqrt{10^3 \pi \rho_C}} \quad (12)$$

$$d_M = \frac{2\sqrt{T_M}}{\sqrt{10^3 \pi \rho_M}} \quad (13)$$

Here ρ_C and ρ_M are unknown densities of weft and warp yarns. These densities are combinations of densities of fibers ρ_F and air ρ_A according to the packing of fibers in yarns. The values ρ_C and ρ_M are therefore function of twist and method used for yarn creation. For the moderate level of twist it has been empirically found that

$$\rho_F / \rho_C = 0.525 \quad (14)$$

and this correction can be imposed to the relation (12) for computation of d_C. The same procedure can be adopted for computation of d_M. More realistic are elliptical shapes of yarns

3. CHARACTERIZATION OF PERMEABILITY UNIFORMITY

For textiles which act as a barrier against particles, permeation is necessary to ensure not only the mean porosity but the uniformity of porosity as well. The uniformity of porosity can be evaluated from air porosity AP_{ij} measured in the individual cells of rectangular mesh. Mesh used in this work is shown in Fig.1.

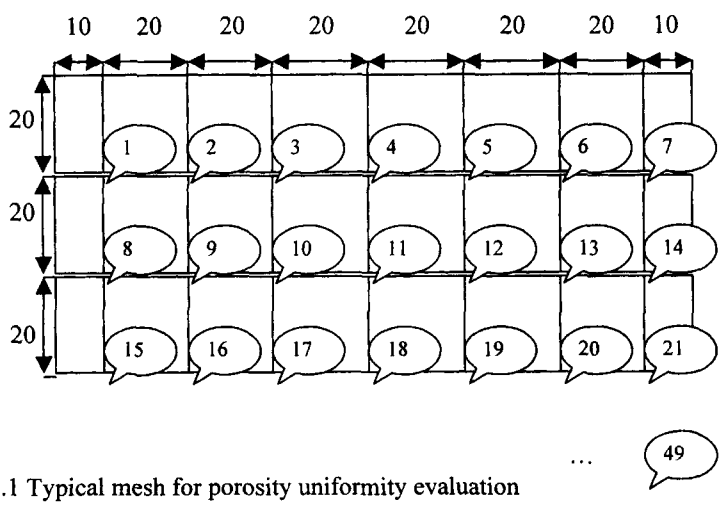

Fig.1 Typical mesh for porosity uniformity evaluation

For mesh in Fig. 1 the number of rows i = 7 equals to the number of columns j = 7.For the measured values AP_{ij} smoothed surface can be created by using e.g. bivariate cubic splines. For description of uniformity in the weft and warp directions the division oh the total coefficient of variation CV can be used. In the work[2] is derived, that CV can be expressed by means of the forms

$$CV^2 = CV_O^2 + CV_{OU}^2 \quad (15)$$

or

$$CV^2 = CV_{UO}^2 + CV_{UO}^2 \quad (16)$$

Symbol CV_O^2 means variation coefficient in the warp direction and CV_U^2 is variation coefficient in the weft direction. The CV_{OU}^2 and CV_{UO}^2 are cross products variation coefficients.

Permeability uniformity can estimated by the two way ANOVA model in the form[1]

$$AP_{ij} = m + \alpha_i + \beta_j + c\alpha_i\beta_j \quad (17)$$

where m is total mean, α_i are effects of rows (warp direction), β_j are effects of columns (weft direction) and c is one degree of nonadditivity parameter. By using of the ANOVA the following hypotheses can be tested:

$H_0 : \alpha_i = 0$ i.e. uniformity in the warp direction

$H_0 : \beta_j = 0$ i.e. uniformity in the weft direction

The realization of tests and estimation of ANOVA model parameters is described in the book [1].

4. EXPERIMENTAL PART

The clean room textiles produced by SPOLSYN company Ceska Trebova Czech Republic were investigated. These textiles are designed for the clean room class of 10. Textiles are weaves composed from polyester fibers. From individual textiles the 5 samples 10x10 cm were randomly selected. Basic parameters of textiles are summarized in the Table 1.

Table 1. Basic parameters of textiles

Textile	W_P [kg/m^2]	t_W [mm]	T_M [tex]	T_C [tex]	D_M [1/m]	D_C [1/m]	d_M [mm]	d_C [mm]
Aralka	0.102	0.18	8.8	11.5	6400	3200	0.094	0.108
Argos	0.141	0.25	17.6	18.4	4400	3000	0.133	0.136
Avila	0.077	0.14	10.0	8.8	4300	3200	0.100	0.094
Arnika	0.105	0.19	8.0	13.6	6600	3200	0.090	0.117

Thickness t_W was measured at load 0.13 kPa. The warp and weft fineness are computed from weights of 10 cm long portions of yarns. Yarns diameters were computed from relations (12) and(13) for the case of most dense arrangements (six neighbors) i.e. $\rho_F / \rho_C = 0.907$.

The air permeability was measured under standard conditions.

The porosities were computed from the relations described in the section 2. Results are given in the Table 2.

Table 2 Air permeabilities and computed porosities of clean room textiles

Textile	P_W [1]	P_{HW} [1]	P_{CF} [1]	AP [cm^3/cm^2s]
Aralka	0.59	0.59	0.26	26
Argos	0.59	0.58	0.25	22
Avila	0.60	0.60	0.40	36
Arnika	0.60	0.60	0.25	30

The permeabilities in the individual cells of the mesh shown on the Fig. 1 were measured under the same conditions as individual air permeabilities. Set of AP_{ij} was obtained for each textile.

5. RESULTS AND DISCUSSION

The computed porosities of investigated textiles are in the very narrow range (see Table 2). The differences between air permeabilities are also very small. It is not possible to estimate relation between air permeability and porosity. In our previous investigations the linear dependence between these characteristics have been found [3].

From the sets of AP_{ij} values measured on the mesh defined on the Fig. 1 were computed variation coefficients CV_O and CV_U. Results are given in the Table 3.

Table 3. Coefficient of variation in the weft and warp directions

Textile	CV (total)	CV_O (warp)	CV_U (weft)
Aralka	6.36	5.43	3.31
Argos	7.41	4.74	5.69
Avila	14.12	11.90	7.60
Arnika	4.40	1.75	4.51

The variation coefficients in the warp and weft directions are relative high. Analysis of variance support this result. The two way ANOVA shown that the uniformity assumption is accepted only for ARNIKA and warp direction. For other textiles in both directions are effects significant and uniformity assumption cannot be accepted.

The variation of permeability is clear from smoothed surfaces. Fig. 2 shows the contour graph of bivariate spline smoothed surface for Argos and Fig. 4 is the smoothed surface.

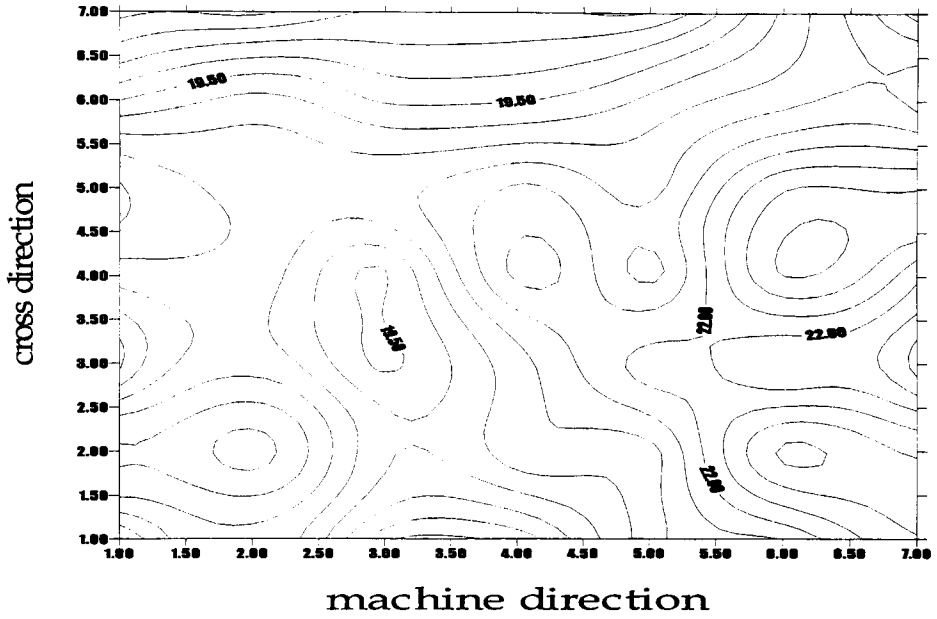

Fig. 2 Contour graph of permeability uniformity for Argos

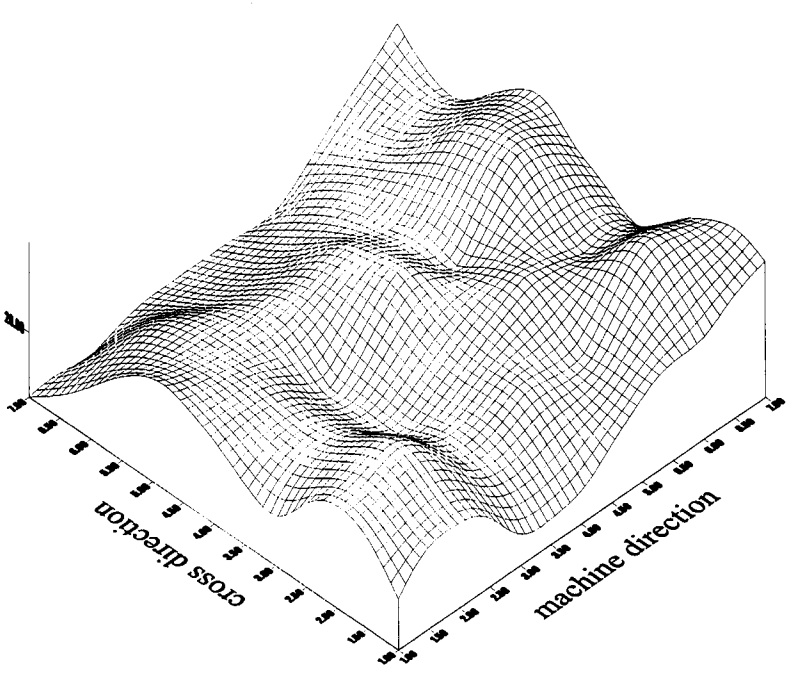

Fig. 3 Smoothed surface of permeability uniformity for Argos

5. CONCLUSION

The porosity and air permeability of clean room textiles were measured. The technique for evaluation of permeability uniformity from air porosity has been proposed. The tested fabrics were non-uniform in both weft and warp directions.

The permeability uniformity can be used as one criterion for estimation of clean room textiles quality. In the cases, where these textiles are used in hospitals, uniform permeability is required from the point of view of good protection against dust particles and microorganisms. The mean value of permeability here is too optimistic.

ACKNOWLEDGEMENTS: This work was supported by the Czech National Grant Agency (grant No. 106/99/0372) and Czech Ministry of Education Grant (grant No. VS 97084)

6. REFERENCES

[1] Meloun M., Militky J., Forina M.: *Chemometrics for Analytical Chemistry*, vol 1, Ellis Horwood, 1992

[2] Cherkassky A.: Surface Uniformity of Nonwovens, *Text. Res. J.* **68,** 242 (1998)

[3] Militký, J.-Trávníčková, M.-Bajzík, V.: Air Permeability and Light Transmission of Weaves, *Vlákna a textil* **5,**31, 1998

14. Influence of the Sterilisation on the Properties and Performance of O. R. Disposable Garments

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INTRODUCTION

In West Europe, the production and consumption of medical textiles have grown, specifically the single-use products, such as O. R. garments and drapes.

This increase is related to the appearance of new and dangerous infectious diseases, such as AIDS, Hepatitis B, etc. Whereas O. R. garments were first used to protect the patient from the physician, the transmission of blood-borne pathogens has focused now on the material's ability to protect the physician from the patient.

Here the importance of sterilisation becomes readily understood, as the state of being free from viable micro-organisms. The primary purpose of sterilising an item is to destroy all living microscopic organisms, reducing the danger of hospital acquired infections. However, the impact of the sterilisation process is sometimes too severe to the sterilised materials.

The manufacturers of these products generally specify the study of the properties from the material used before sterilisation, unknowing the changes that can appear after the sterilisation, mainly because of the interaction of different materials used to produce the garment. A product that was designed successfully could after a sterilisation process be transformed in an unrecognisable piece of material.

Since, the recommended sterilisation methods for single-use products are the low temperature sterilisation, we studied the properties of O. R. garments - disposables before and after the submission to several low temperature sterilisation methods.

We also studied the joining methods in the manufacturing of O. R. garments. The influence of the sterilisation methods over the unconventional joining methods has great importance in the performance of this product. The individual materials could perhaps resist several sterilisation methods, but it is impossible to predict the behaviour of the material after the assembling.

After the study of the properties and having considered the joining and sterilisation methods, we have drawn concrete conclusions. These conclusions will be presented at the conference to support the manufacturing industry as a matter of quality assurance measures and on the other hand the end-users, to inform and help them to select the products according to these criteria.

MATERIALS

Surgical gowns can be simple or reinforced. In the case of operation room gowns it is advisable to use the reinforced gowns.

The gowns must be reinforced at the thoracic and abdominal region and also the forearms must be reinforced. (Figure 1). These parts of the gowns are considered the critical zones with the major possibility to come in contact with blood and other saline solutions present during an operation. The gown must prevent the contact of these solutions with the medical and nursing staff, but also protect the patient from contamination by pollutant particles in the air during the operation.

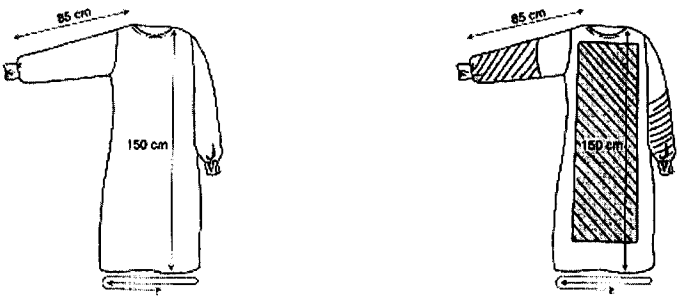

Figure 1 - Simple and reinforced gowns

The European Committee for Standardization (CEN) has a workgroup CEN/TC 205 responsible of the "Non active medical devices". According to the EC Directive 93/42/EEC, surgical clothing is considered to be medical devices, independently if they are reusable or disposable gowns.

In our study the gowns are disposables and made from different types of nonwovens, with under or outer layers to reforce the barrier function.

GOWN	MATERIAL	
	Outer Layer	Inner Layer
Type 1	Nonwoven	Laminate
Type 2	PE	Nonwoven
Type 3	Nonwoven	Laminate

Table 1

Note: Nonwoven the same for all types studied
Laminate - the same for all types studied

PROPERTIES STUDIED

The European Disposables and Nonwovens Association (EDANA) has published an increasing number of test methods that it recommends be used for measuring various properties of nonwovens or other related products. They have several recommended evaluation procedures for several products. For gowns the document (EREP 610.0-93) is an aid and a guidance for assessing properties required for nonwovens in surgical gowns.

The International Nonwovens and Disposable Association (INDA) has more impact in the United States of America. It has also a number of test methods for gowns, some different from the EDANA test methods and because of that must also be analysed and considered.

This field of research is still very unknown and we must consider all information available to choose the most important properties for this type of product. We indicate in Table 2 the properties tested.

Property	Test Method	Reference	Units
Strength:	Nonwovens Tensile Strength and Elongation	EN 29073-3	N %
	Nonwovens Burst	ERT 80.2-96	KN/ m²
Alcohol Repellency	Inda Standard Test	IST 80.6-92	Repellency Rating
Liquid Repellency	Wet Barrier - Hydrostatic Head	EN 20811	mbar/min
Comfort:			
Drapeability	Nonwovens Drape	ERT 90.3-96	
Flexural rigidity	Bending Length	ERT 50.4-96	mNcm
Breathability	Air Permeability	ERT 140.1-81	l/m²/s
Mass per Unit Area	Mass per Unit area	EN 29073-1	g/ m²

Table 2

JOINING METHODS

The use of unconventional joining methods (adhesives, bonding and ultrasonic welding) in the critical zones has the advantage over the conventional sewing techniques, in that no holes are created by the stitches, avoiding the passage of liquids through the holes. If the material to reinforce is stitched, the presence of these materials would be irrelevant for the barrier function.

The joining methods in the manufacturing of surgical gowns must be studied with great care and also the influence of the sterilisation methods over the joining methods has great relevance to the development of this type of product.

The individual materials could perhaps resist the several sterilisation methods, but it is impossible to predict the behaviour of the material after joining.

Table 3 indicate the presentation and the application of the joining methods used for the different types of gowns studied.

These different joining methods were studied in our research before and after different sterilisation methods, see Table 3.

GOWN	PRESENTATION	APPLICATION
Type 1 **Type 2**	Adhesive	Roller (cold)
Type 3	Bonding with Adhesives in Fibre Form	Heat Pressing

Table 3

PURPOSE AND IMPORTANCE OF STERILISATION

The primary purpose of sterilising an item is to render it safe for use by destroying all living microscope organisms. An object can never be almost, partially or practically sterilised: is it either sterilised or not sterilised. Because bacteria multiply very quickly, the sterilisation process must be absolute. Even a few organisms invading the patient's body during a surgical procedure can reproduce rapidly and contribute to post-operative complications.

The European Norm 556 defines sterility as the state of being free from viable micro-organisms ($\leq .1 \times 10^{-6}$).

Four common types of sterilisation methods are in use today: gas, irradiation, steam autoclave and dry heat. The first two types of sterilisation are also called low temperature sterilisation methods and the last two types, high temperature sterilisation methods.

Many sterilisers use saturated steam under pressure, but this method is not practical for plastics and other synthetic materials because they are damaged at high temperatures. These materials require low-temperature sterilisation.

Gamma radiation is the most widely used low temperature sterilisation method after EtO and the fastest growing of all sterilisation methods.

EtO is a dominant sterilisation technique that is declining in use due to the following reasons:

- physical properties change in polymers due to reactivity of the gas;
- length of degassing time, product airation and elimination of gas toxic residues;
- absorption and adsorption of the gas as, leaving residues and damaging the optical properties of the polymer;
- the environmental protection agency has found EtO to be mutagenic and has initiated steps to restrict its use; and
- the operator safety (because of toxic gas residues).

Nevertheless EtO is the least aggressive form of sterilisation for many materials. The replacement of the most common EtO carrier gas - CFC-12 (Freon) - with non-ozone depleting alternatives, such as carbon dioxide and chloro-tetrafluoroethane, will cause EtO to remain a viable choice for many users of sterilisation services.

RESULTS AND DISCUSSION

The results were studied using statistical methods:

- Test of the variance (Fo);
- Test of the means by the t-Student test;
- Analysis of variance (Fc).

We have studied and compared the results before and after sterilisation, to finally indicate the effect of these methods over the studied materials and related properties.

We experimentally verified that the lamination or joining, in the presence of adhesives of two systems may result in important changes in the original properties. In this case the properties of the fabrics, determine the potential end uses of the fabric.

CONCLUSIONS

After the study of all the properties and having considered the joining methods as well as the sterilisation methods, we make concrete conclusions about the most suitable sterilisation method for each gown. Most of the properties were improved by using one specific sterilisation method (Table 4).

Therefore, we conclude:

Property	Gown		
	Type 1	**Type 2**	**Type 3**
Nonwovens Tensile Strength and Elongation	EtO	Gamma	EtO
Nonwovens Burst	Gamma	EtO	EtO
Alcohol Repellency	EtO/ Gamma	EtO/ Gamma	EtO/ Gamma
Liquid Repellency (Wet Barrier - Hydrostatic Head)	EtO	EtO	EtO
Drapeability	EtO/ Gamma	EtO	Gamma
Flexural rigidity	EtO	EtO	EtO/ Gamma
Air Permeability	EtO	EtO	EtO
Mass per Unit Area	Gamma	EtO	Gamma

Table 4

So the most suitable sterilisation methods, taking all results in consideration for all types of gowns studied, are the following:

Gown	Sterilisation method
Type 1	EtO
Type 2	EtO
Type 3	EtO

Table 5

In future studies we will also consider electron beam and beta radiation as well as application of plasma sterilisation.

References

(1) Werner, H. P.; Feltgen, M., "Quality of Surgical Drapes and Gown Materials". Infection Control and Healthcare, February, 1998

(2) "The Effect of Sterilization Methods". Plastics Design Library, 1994, USA.

(3) Araújo Marques, M.J.; Cabeço Silva, M. E.; "The Properties of Nonwovens in the Healthcare Industry". Tessili per impieghi Tecnici, December, 1996.

(4) Araújo Marques, M.J.; Cabeço Silva, M. E.; "The Design of Surgical Clothing - Application in the Healthcare and Hygiene Industry". Tessili per impieghi Tecnici, December, 1997.

(5) Araújo Marques, M.J, "Contribuição para a Definição de Propriedades de Materiais Têxteis Hospitalares Descartáveis". Tese de mestrado, September, 1997.

15. Formation of Creases in Bedsheets – A Cause of Decubitus

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Abstract

In this paper the results of a study on the formation of creases in bed sheets will be discussed. Several factors that can be expected to play a role have been studied. The factors are shape of the body, applied pressure, tension of the fabric and softness of the mattress. Several types of fabrics wre compared. In the first phase a test set-up had to be developed and relevant characteristics had to be determined. The conclusions were that all factors considered have an influence on the formation of creases, showing many complex interactions. Also different types of fabrics show totally different behaviour.

1. INTRODUCTION

People spending most of their time in bed have reduced circulation of the blood. Combined with local pressure, the body cells start to suffer from lack of nutrients and oxygen. Waste products cannot be removed efficiently anymore. The cells may be damaged and eventually they will die. Research has shown that necrosis leads to irreversible damage at pressures higher than 6250 Pa applied during more than 2 hours[1].
This process causes typical injuries called "*decubitus*" or bedsores .
Bedsores have been known for thousands of years. People who are totally immobilised suffer from it, mainly old people and patients with neurological injuries. Bedsores cause the time needed to care the patients to increase by 50%, and prolongs the residence time at the hospital by nearly 40 days.
A huge research effort has been spent in medicine to analyse, treat and prevent bedsores.
The bedsheets used in hospitals however, seem to date from the past centuries. No effort is made to make new textile materials that could help in the prevention of bedsores.
Yet there are several characteristics that can obviously be improved in this respect:

- A textile with a high water transport and absorption capacity keeps the skin dry, which is an important factor,
- The presence of creases in bed sheets leads to high local pressures at the skin, and as a result to increased risk on bedsores.

In this presentation the first research results on formation of creases are reported.
The paper consists of two parts, namely the actual test method[2] and the evaluation of different textile materials[3].

2. TEST METHOD

The research programme consisted of two phases. The first phase focused on the test method. In a second phase, a set of different textile materials were studied in view of their propensity to form creases.

2.1 Test set up

An attempt was made to take into account the variations of real conditions as close as possible:

- The textile sample is put on a (small scale) water mattress,
- The influence of using various underlayers is simulated by putting one or more layers of nonwoven under the textile,
- The tension of the fabric is varied simply by hanging weights at the edges of the fabric,
- The patients have different body shape at different parts of the body: objects with different shapes (round, elliptic, square, ...) were pressed on the textile;
- Patients have various weights: the pressure of the object was varied.

A schematic overview of the test set-up is given in fig. 1.

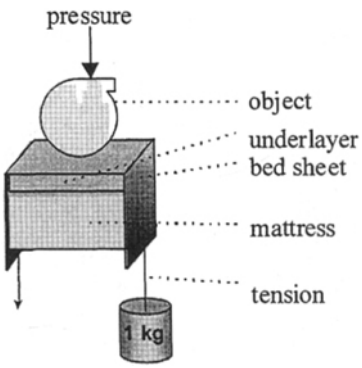
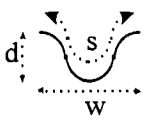
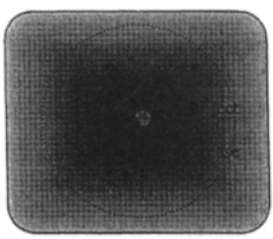


Fig. 1 - Principle of test set-up.

Depending on the test conditions, creases appear in the bed sheet. The main parameters of creases are their number, length (l), depth (d), width (w) and width measured along the crease (s), as is illustrated in fig. 2.





a. cross section of a crease b. top view of mattress

Fig. 2 - Parameters of crease formation

A fifth parameter was calculated as the ratio (r) between width and width measured along the crease : $r = \frac{s}{w}$.
This parameter indicates whether the crease is smooth (r small) or deep and sharp (r large). Smooth creases are less harmful in view of generation of bedsores.

A preliminary design was made in order to quantify the sources of error on the measurements, so that the number of tests required for a certain accuracy can be calculated. After this the influence of the following parameters was studied:

- shape of the object;
- pressure;
- number of layers on the mattress (thickness and softness of the underlayer); and
- tension of the bed sheet.

The measurements were repeated at different distances from the object.

2.2 Results

2.2.1 Sources of variation

Two sources of variation have been considered, namely the variation of the actual measurements and the variation between measuring spots. For this the sheet was put on the mattress, taken away and put on again repetitively. The measurements were repeated each time. The reproducibility of the results initially was very high. It could be reduced by extreme caution in putting the sheet on the mattress.
The results of an anova for the length of the creases are the following:
MS between groups: 32.3 (= σ_{with}^2 + 25. σ_{betw}^2)
MS within groups: 0.13 (= σ_{with}^2)
From this it can be concluded that the variation on the actual measurement is negligible as opposed to the variation between measuring spots. One repetition at ten different spots allows to come to an error of about 10% (confidence level 95%).

2.2.2 Significant factors

A first conclusion was that the distance from the object where the parameters of the crease were measured is relevant in that the actual values are affected, but the trends remain the same. This is illustrated in fig. 3, where the influence of the number of layers (softness of the mattress) on the depth of the crease (ratio r), measured at distances from 6 to 10 cm from the object is given. So it was concluded that the measuring distance was not really critical, as long as it was kept constant.

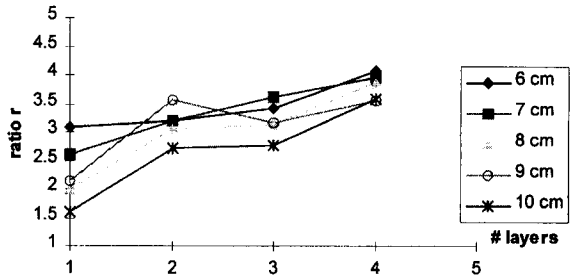


Fig. 3 - Influence of measuring distance from the object on trends for different numbers of underlayers.

The underlayer also plays an important role: a softer underlayer will enhance the formation of creases (Fig. 4) and they will be deeper (Fig. 3). Fig. 4 also shows the importance of the body shape: critical body areas are the buttocks (large ball), whereas the legs (cylinder) and the elbows (small ball) are less threatened. This is confirmed by practice, although it is assumed to be caused by the pressure distribution of the body.

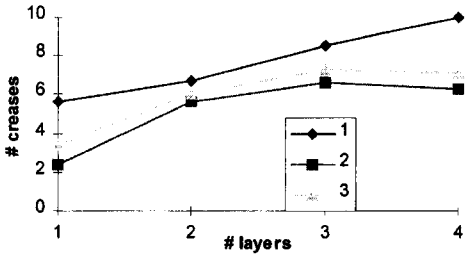


Fig. 4 - Influence of the softness of the mattress on the number of creases for 3 different objects (1 = large ball, 2 = small ball, 3 = cylinder)

Of course the pressure does play an important role too, as can be seen by fig. 5. It also shows that increasing the tension of the bedsheet can help to reduce the number of creases. It can even compensate for higher weights.

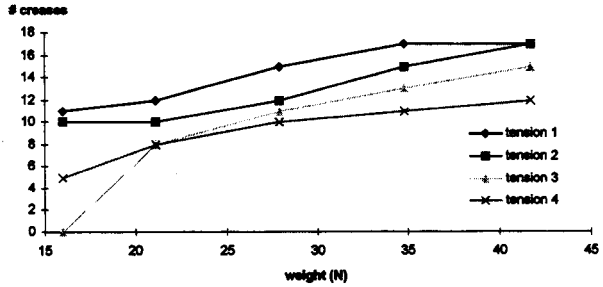


Fig. 5 - Influence of the pressure applied on the object on the number of creases, at different tensions of the bed sheet (1 = low, 4 = high).
Not only is the number of creases reduced by applying a higher tension, they are also less deep (Fig. 6).

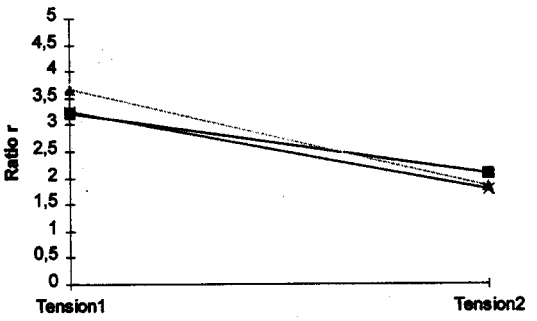


Fig. 6 – Influence of tension on depth of the creases.

The following general trends were identified:

- both the number and the depth of creases increases with increasing pressure, indicating unfavourable conditions for heavy patients (high pressure + many creases = higher local pressure);
- the highest depth of the creases can be found near the object;
- the shape of the object has a significant influence: the bigger the surface of the object the more creases will be formed and the deeper they will be; and
- both the number of creases and the depth increase with increasing number of layers on the mattress (i.e. increasing softness) and with decreasing tension.

Generally speaking all effects are less pronounced at higher tension of the bed sheet.

2.3 Role of the textile material

Six different textile materials were analysed, woven, nonwoven and knitted fabrics having different constructions and weights.

2.3.1 Experimental

This part of the research has focused on the width and the depth of the creases, as expressed above. The sheets were analysed according to the test method described above, with the following test conditions:

- Object: large ball, small ball;
- Weight: 2660 g;
- Tension: 4*320 g;
- Measuring distance: 8cm from the centre of the object.

The fabric deformability has been estimated using the drape test[4]. In this test a fabric is hanging freely over a cylindrical disc. Gravity causes the fabric to hang, and its resulting deformation of a fabric is measured. Deformation is defined as the change of the projected area of the fabric after projection on a horizontal plane.
Secondly the stiffness is determined by measuring the force required to drag the fabric through a hole in a plate[5].
The number of repetitions to come to a relative error below 10%, resp. 5% for creases, resp. mechanical properties, was determined in advance.

2.3.2 Results

The results of the experiments are summarised in table 1:

Table 1 – summary of test results of different textile materials

Type	Crease Width	Crease Depth	Ratio r	Drape	Stiffness
Woven	11.8/11.6	3.8/3.4	0.32	54.3	11.4
Woven	10.2/10.5	2.3/2.4	0.23	41.8	8.7
Knitted	0/0	0/0	0.00	4.7	12.9
Woven	7.6/9.7	2.1/2.2	0.28	55.9	9.4
Woven	7.6/8.0	2.6/2.9	0.34	63.5	9.8
Nonwoven	10.3/10.7	3.4/3.8	0.33	75.7	21.9

The table shows that a knitted bedsheet definitely has the lowest propensity to form creases: no creases were recorded at all.
There are differences between different woven fabric types. The nonwoven bedsheet has turned out to be quite stiff, but it could not be distinguished from the woven fabric.
Regression analysis must be interpreted with care because of the small amount of data. The best correlation is found between drape and the ratio r (0.96, p 0.002). the correlation between drape and width, resp. depth is significant as well (0.86, resp. 0.92). Correlations with stiffness are both low and insignificant.

3. CONCLUSIONS

In this paper an attempt has been made to study the factors that contribute to the formation of creases in bed sheets in view of the generation of decubitus.

A reliable test method has been established to measure the propensity to form creases as well as the type of creases that were formed. Existing test methods were used to analyse the mehcanical properties of the textile materials.
It is concluded that all test conditions under consideration significantly influence the formation of creases. However there seem to be many complex interactions.
Heavy patients have a higher risk of bedsores. The thickness of the underlayer should be small, and the bedsheet should be wrapped around the mattress as tight as possible.
Further work can be carried out with regard to automation of the test method and on the properties of the bed sheet that determine the formation of creases. So far it seems that the drape test gives a proper indication of crease formation. Theoretical analysis can support this study, whereby the formation of creases can be considered as the occurrence of buckling of the textile material.

4. REFERENCES

[1] NN., 'Decubitus', *Journal of Medicin*, 51, n° 12, 1995.
[2] O. Plaza Latorre, 'Study Of Crease Formation In Bed Sheet', Thesis presented at the Department of Textiles, Universiteit Gent (Belgium), 1997.
[3] J. Obiols-Cirera, 'Research On The Formation Of Creases In Bedsheets', Thesis presented at the Department of Textiles, Universiteit Gent (Belgium), 1998.
[4] BS5058(1973)[4].
[5] N. Pan, K. C. Yen, 'Physical interpretation of curves obtained through the fabric extraction process for handle merasurement', *Text. Res. J.* 62 (5), 279-290 (1992).

16. The Design of Needlefelts to Control the Flow of Liquids in Incontinence Products

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Introduction

This paper describes some of the experimental work that is being carried out as part of a MEDLINK project on the design of reusable incontinence products, especially bedpads. This work also forms part of a PhD project.

In the UK, the NHS spends about £80m a year on incontinence pads and appliances, and nursing homes a further £40m – most of these are disposable. Reusable i.e. washable products have been available for the past 15 years but interest in them has only occurred recently because they potentially represent a significant saving in money compared to disposables. On a per use basis, reusables are cheaper than disposables provided that they last more than about 100 washes – many are guaranteed for over 200 washes. Interest in reusables is increasing in Europe and North America. In the UK some health authorities are replacing disposables with reusables wherever possible.

Reusables have shortcomings which need to be overcome to increase their acceptability in the market. These include:

1. Leakage

The capacity of a typical bed pad is one litre – typically they are not required to hold more than 300ml, and yet they leak.

2. Dignity in use

Users have to go to bed unclothed beneath their waist so that their night-clothes do not stop urine reaching the bed pad. This is unpopular with end users.

3. Skin dryness

There is a tendency for the user's skin to stay wet.

4. Drying after washing

Although only a proportion of the absorption capacity of a pad is exploited in use, they absorb to full capacity during washing. Tumble drying can then take 45min and is expensive.

One of the aims of this project is to design a bedpad or garment or combination of bedpad and garment, which could overcome these problems. In this paper we will concentrate on bedpads.

Our approach to overcoming these shortcomings is by considering the several functions that a pad needs to achieve in managing liquid flow, and how the components of a pad can be engineered to provide those functions.

A typical reusable bedpad comprises three homogeneous layers. These are:

- an absorbent layer which is usually a needlefelt of a cellulosic, polyester or a blend of both
- a top fabric which is adjacent to the skin and needs to be smooth, soft, flexible and allow rapid transmission of liquid, so avoiding pooling.
- An impermeable backing layer.

Ideally when urine is discharged, it penetrates the surface of the pad, and readily is rapidly moved away from the user's skin, to a storage area. During the night there might be several discharges, each of which needs to be similarly removed.

As the user rolls over, local pressure can cause urine to come out of the structure ("wetback") and rewet the user's skin. This can feel uncomfortable and can cause skin damage.

The desirable properties of a bed pad include:

- conformability, softness and flexibility
- adequate absorbency
- a top fabric which allows rapid transmission of liquid and avoids pooling
- rapid flow of liquid from the entry point
- adequate retention of liquid under pressure to prevent wetback or leakage.

The physical properties thought relevant are:

Absorption rate: the product must allow urine to enter the pad structure sufficiently quickly to prevent pooling on the surface and leakage over the surface. The peak flow rate for a man is around 20ml/s and for a woman 30ml/s. If the product at the point of entry does not permit that throughput, then liquid will spread rapidly across the surface. The distance it spreads is determined by the permeability of the fabric, the rate of discharge and the viscosity of the liquid.

Permeability: this is a measure of the ease with which a liquid will pass through the product when a pressure gradient is applied.

Absorption capacity: the product must hold approximately three discharges per night – a typical bed pad has a far greater theoretical capacity than is ever used.

Wetback: as the user rolls over, urine can be squeezed out from the pad.

Drying rate after washing: we need structures which will absorb and contain liquid easily during use but release it easily after washing.

Wicking rate: the product needs to wick large quantities of liquid, quickly. In use, a bed pad is not a flat surface and so wicking at an angle to the horizontal needs to be measured. In this paper we report on preliminary work on wicking for some needlefelts. Needlefelts are commonly used because of their high capacity per unit cost.

Design concepts

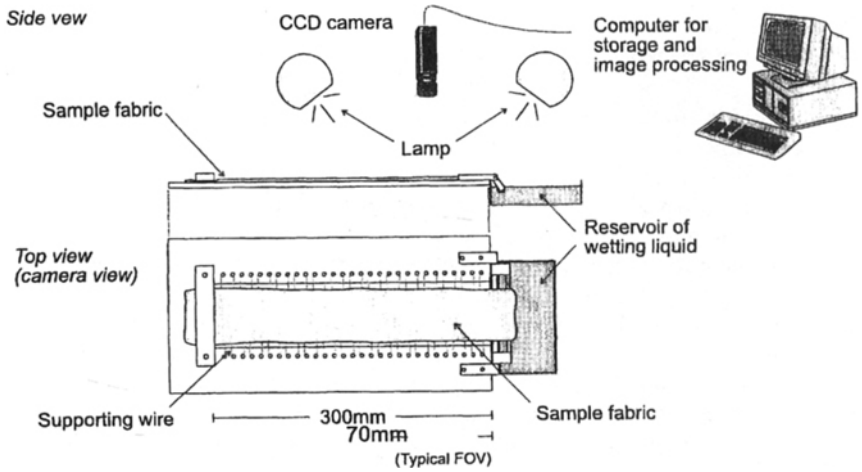
The discharge, of about 175ml over, ten seconds, say, spreads out through the bedpad structure, from the impact point. For a single layer, homogeneous needlefelt, when the forced flow stops, there is a risk of wetback as the user moves. Therefore we need to remove liquid from the area of most likely contact within a reasonable time. Although one could envisage a system of pumps, a cheaper approach is to use wicking. In this project we are considering wicking as the transport mechanism that is available, after forced flow has occurred

A key design objective is therefore to find a structure which wicks a significant mass of liquid to a distance such that the possibility of wet back is low.

Wicking

Wicking is the spontaneous transport of a liquid into a porous medium by capillary forces. As such it provides a powerful mechanism with which the material designer can influence the distribution of liquid within an absorbent structure.

Capillary driven flows of liquids have been studied since the beginning of this century, although the phenomenon is still not well understood. The wicking performance of a textile is dependent on: fibre surface energy and morphology, capillary geometry, liquid imbibition properties and interactions between the liquid and fibre surface (interfacial tension and contact angle).



1. Apparatus used to support sample and image horizontal wicking

Test procedure

The primary wicking mechanism at work in a bed pad is the movement of liquid parallel to the plane of the material. Various laboratory tests have been developed to measure this type of wicking [1].

Here, a 50mm wide fabric sample is supported on a series of parallel nylon monofilaments (to minimise any effect the supporting surface may have). One end of the sample is pinned and held into an empty reservoir which rests on a balance. The wicking liquid, in this case, water is lightly coloured using Terasil Red (0.02g/l). This liquid is then held above the reservoir, and released at the start of the experiment using a solenoid valve.

As liquid wicks through the fabric images are captured by a CCD camera and computer, at a rate of three per second. The images are stored, with their time of capture for analysis. Typically 750 images are collected per run, each image comprising 768x572 pixels covering an area of fabric 55x70mm (see fig. 1) . Mass readings from the balance, synchronised to the start of imaging, are recorded simultaneously.

Image processing

A sequence of grey-scale images is collected recording the development of the wetted area of the fabric. Contrast between the fabric and the red liquid is enhanced by use of a green filter.

An image in which there are no wet pixels is used to determine the change in intensity for each pixel at a given point in the sequence. Once this difference exceeds a threshold value these pixels are marked as wet. The wet area can then be estimated from the resulting binary image (2).

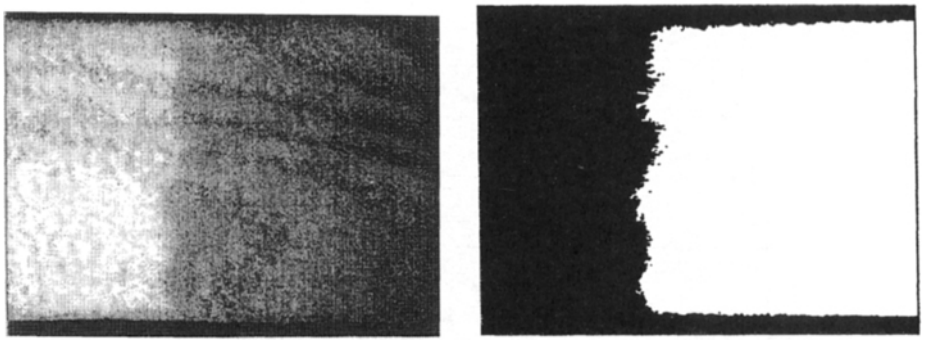
Samples

Viscose needlefelts were made from 1.7, 3.3 and 5dtex fibres. Fabrics were made on Texon's pilot line at Leicester. The yield was nominally 450g per sq m.

"Light" and "heavy" needling regimes were used.

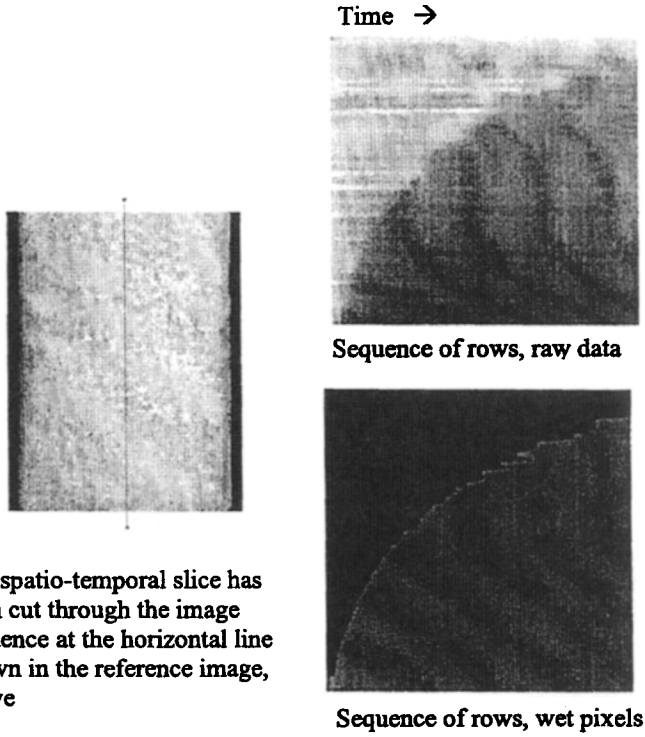
It was thought likely that finish would affect the results, and so each fabric was tested before and after being lightly hand washed.

Details of the samples made are given in Table 1 and the key to experiments in Table 2.



Captured image 'Wet' pixels in captured image

2. Example image captured during wicking, the wet area appears darker due the red dye and green filter. Examining the intensity change in each pixel allows identification of wet pixels, shown as white in the second image.



3. Composite images showing wicking throughout a sequence. A single column of pixels has been extracted from each image. These columns are shown together allowing the time evolution of the wet distance in a small portion of the sample to be displayed.

Sample	dtex	Needling	Fabric area density (g/m^2)	Fabric thickness (mm)
V1	1.7	light	477	5.5
V2	3.3	light	453	5.1
V3	5.0	light	510	6.3
V4	1.7	heavy	485	3.5
V5	3.3	heavy	456	3.6
V6	5.0	heavy	490	4.3

Table 1. Key to samples

Code	Experiment
V*n*	Horizontal wicking, viscose sample in machine direction
V*n*v	Vertical wicking, viscose sample in machine direction
V*n*vx	Vertical wicking, viscose sample in cross machine direction
V*n*vw	Vertical wicking, washed viscose sample in machine direction
V*n*vwx	Vertical wicking, washed viscose sample in cross machine direction

Table 2. Key to experiments

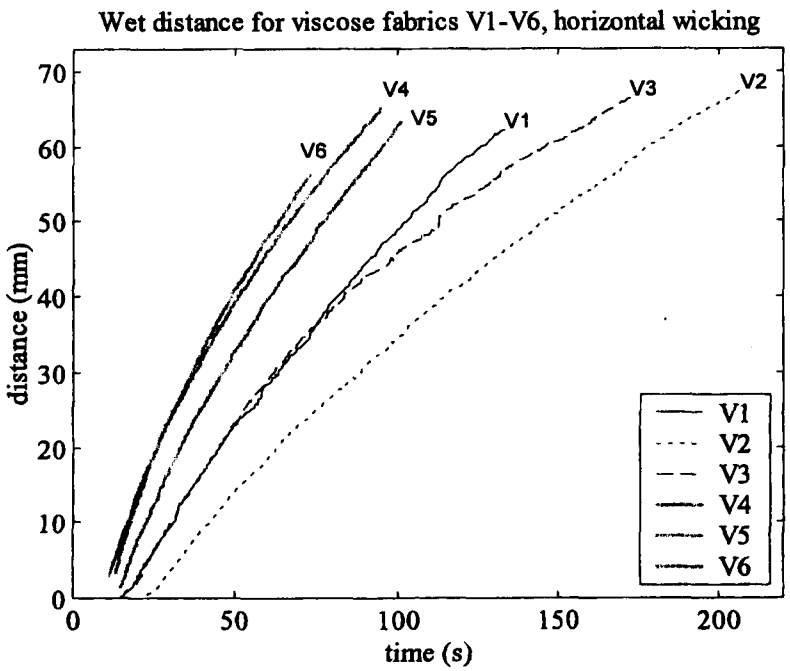
Sample and experiment	Wicked distance (mm)	Wicking rate (mm/s)
V1	28.39	0.54
V2	18.43	0.45
V3	28.91	0.53
V4	46.02	0.63
V5	39.68	0.63
V6	47.80	0.65
V1v	15.47	0.14
V2v	7.91	0.12
V3v	6.39	0.05
V4v	33.97	0.30
V5v	19.69	0.20
V6v	18.81	0.16
V1vx	25.19	0.13
V2vx	13.75	0.10
V3vx	11.33	0.08
V4vx	43.35	0.34
V5vx	29.39	0.20
V6vx	25.53	0.16
V4vw	39.47	0.28
V5vw	31.41	0.17
V6vw	20.42	0.09
V4vwx	43.25	0.33
V5vwx	34.63	0.16
V6vwx	20.42	0.12

Table 3. Wicked distance and rate at 60 seconds

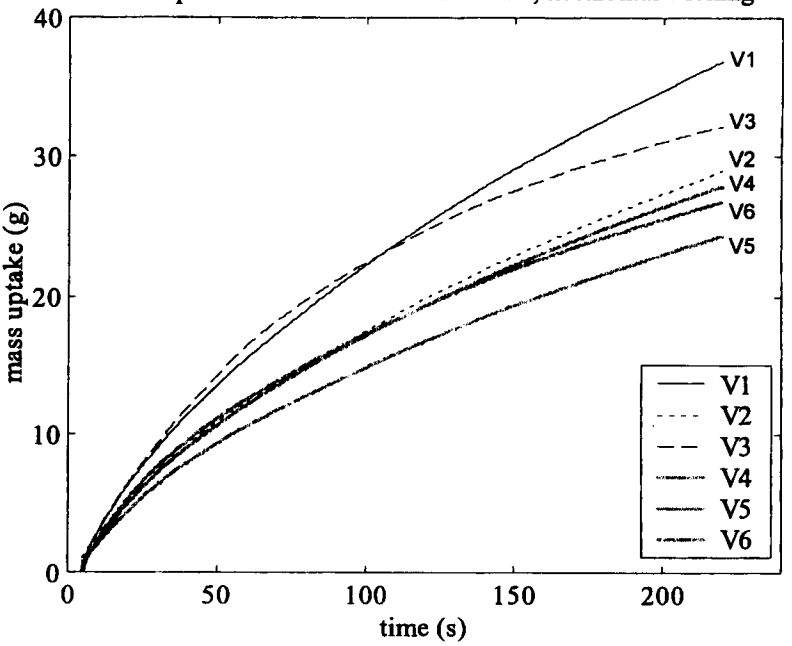
Results

Of course, a bedpad is not a flat structure in use and we propose carrying out wicking measurements at a range of angles. The results reported here are only for vertical and horizontal wicking – at two different levels of needling. (Vertical wicking results are for before and after washing.) For illustration we show the graphs of wicking distance and mass plotted, against time, (machine direction samples, before washing). We are interested in transporting as much liquid as possible well away from the discharge area, in a reasonable time. Therefore we include a graph of mass against wicking distance.

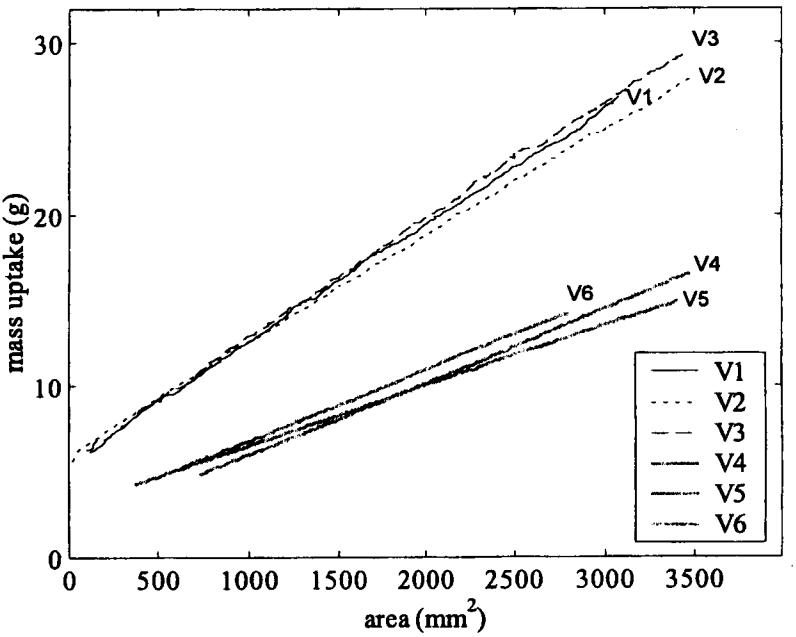
The results for wicking distance and wicking rate after sixty seconds are given in Table 3. There are clear differences between heavily and lightly needled felts, and some suggestion that washing increases wicking distance.



Mass uptake for viscose fabrics V1-V6, horizontal wicking



Mass uptake - area relationship for viscose fabrics V1-V6, horizontal wicking



Discussion

It is clear that the more heavily needled fabrics produce more effective wicking in terms of distance/time, suggesting that the smaller effective capillaries produced by heavier needling, enhance wicking. Using finer fibres might be expected to give faster wicking – the results do not show a clear trend with decitex.

The graph for mass transport by horizontal wicking shows considerable bunching, but with the best results for V1 i.e. a lightly needled felt from low decitex fibres.

Turning to vertical wicking, again the more heavily needled fabrics wick further and, within each group of three felts, those from the lightest decitex fibre, are the most effective.

We have also shown a plot of mass against wetted area. This is chosen to show the ability of the fabric to move a worthwhile mass of liquid, a significant distance from the discharge point. This graph shows no clear differences between felts of different decitex, but the more lightly needled felts give more effective mass/distance transfer. (The same trend is found for vertical wicking).

In simple discharge experiments, we found that pouring 175ml of water (at body temperature) onto a viscose needlefelt produced an approximately circular distribution for the forced flow, which had a diameter of approximately 20cm. The liquid then wicked a shorter distance, approximately 2cm over the next hour – clearly not reflecting the behaviour observed in the horizontal wicking tests.

The reason is that whereas in the usual wicking test, the "reservoir" is a pool of liquid, in the "real life" situation, the reservoir is saturated felt. We therefore have started investigating wicking from a saturated felt.

Conclusions

An imaging technique has been developed to determine the wicking properties of fabrics and applied to viscose needlefelts.

For the range of decitex and the degree of needling investigated, the effective of changing needling conditions has had the more pronounced effect. The more lightly needled fabrics wick more water/distance that the more heavily needled - this is probably because of the larger pore volume.

We are now extending the work to wicking from a saturated felt since this more accurately represents what happens in use.

Acknowledgement: Dr. A. Cottenden, UCL. MEDLINK Project Manager, PhD Supervisor. This research was undertaken within the Postgraduate Training Partnership established between Sira Ltd., and University College London and sponsored by Acordis. Postgraduate Training Partnerships are a joint initiative of the Department of Trade and Industry and the Engineering and Physical Sciences Research Council.

References:

[1] Harnett P. R. and Mehta P.N. A survey and comparison of laboratory test methods for measuring wicking. Textile Research Journal, 54:471-478, 1984.

[2] W. K. Pratt. Digital image processing. New York:John Wiley and Sons Inc, 1991.

Session 4: Wound care

17. Some Aspects of Cotton Leno Fabric Usage in the New Generation of Dressing Materials

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The range of dressing materials manufactured on the basis of textiles is very wide. On the whole, dressing materials can be divided into those which have direct contact with a wound and outer, protective dressings, which are put on those direct ones.

Dressings that adhere to the wound have a big influence upon the way and time of wound healing, and also upon the psyche and general feeling of patients, resulting from the degree of arduousness of keeping these dressings and changing them. For this reason dressings are in the centre of particular interest of medical services as well as producers of dressing materials. With the help of doctors, engineers and technologists employed in health service, research institutes and in industry, trying to take these aspects into account, better and more modern dressing materials are developed. They shorten the time of wound healing and are characterized by improved comfort of use by patients.

Therefore, one should ask a question - what are the desired properties of modern dressing materials, especially these having direct contact with the wound. Among such properties one should mention:

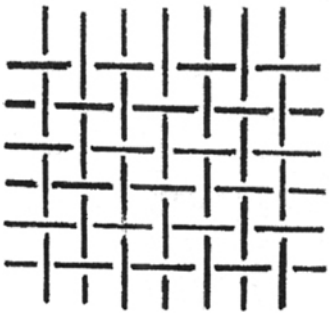
- healing properties, regulated mainly with substances applied to or added to the dressing,
- causing no mechanical injury of a granulating wound,
- decreased adherence surface
- eliminating a possibility of loose fibres getting caught in the wound,
- stable and spatial structure,
- easy penetration of wound secretion to the absorbing dressing,
- not-interrupted process of wound healing - as only the outer gauze compress is changed,
- painless changing of the dressing.

What results from the above is that the influence of the dressing materials used upon the time of wound healing depends both on the textile element (usually cotton gauze) and on chemotherapeutic agents.

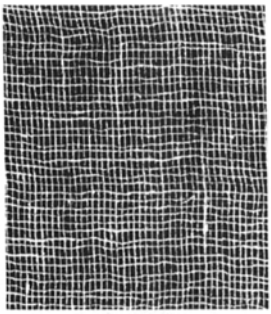
A vast majority of textile dressing materials presently used is made of cotton bleached gauze. This is a light cotton fabric of plain weave, and low density of cloth. The structure of this fabric has been shown in fig.1. The real appeareance of the fabric is presented in fig.2.

A significant weakness of this fabric is its construction, characterized by dimensional unstability, fraying of edges, wooliness and flat surface. In result, dressings produced from such a fabric are characterized by certain undesirable features, ie.:

- a possibility of loose fibres getting caught in the wound,
- a large adherence surface,
- irritating or mechanical injuring of a granulating wound when the dressings are changed,
- prolonged time of wound healing,
- painful changing of dressings.



1. Structure of plain weave



2. Real appearance of gauze of plain weave

The aim of the new generation of dressing materials is to eliminate these weaknesses and to improve the effectiveness of healing wounds. An example of such activity are cotton leno fabrics used for certain dressing materials, ie:

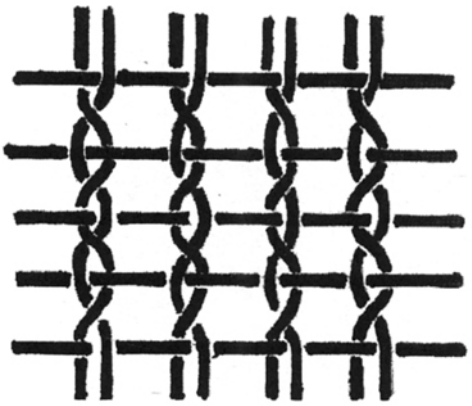
- paraffin and ointment dressing;
- non frying bandage;
- non frying gauze dressing;
- elastic bandage.

Institute of Textile Architecture in Łódź in cooperation with Viscoplast S.A. in Wrocław – the producer of dressing materials in Poland are testing leno fabrics for modern textile dressings including paraffin dressings.

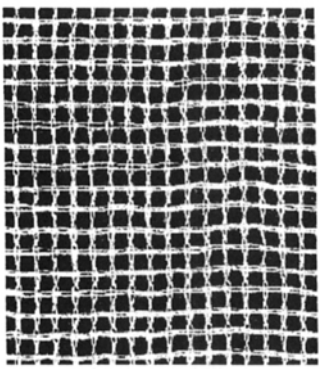
A paraffin dressing consists of a bleached cotton fabric of a proper structure, onto which a layer of soft paraffin material is applied. The paraffin material makes the dressing hydrophobic; thus it does not absorb wound secretion, which can easily penetrate to the absorbing dressing which is placed on the paraffin dressing. Besides, paraffin applied onto the gauze, eliminates the problem of loose fibres getting caught in the wound. Paraffin dressing is chemically neutral, so chemotherapeutic agents, shortening the process of wound healing, can also be applied to it.

Viscoplast SA in Wrocław tested using ordinary gauze for paraffin dressing, but the results were not favourable, due to irregular absorption of paraffin material, clumping of weft and warp threads, folding of the fabric in result of paraffin material application, and crumbling of paraffin material. In all known paraffin dressings, the base for paraffin material is a fabric of leno weave. Only this kind of fabrics meets the requirements for this type of products, and enables a proper technological process of dressing materials production. Applying paraffin on the fabric of such construction is easier, more regular and stable. Fabric of leno weave as a base for paraffin material in paraffin dressings is not subject to defibering and keeps the paraffin well. The structure of a fabric of leno weave used for paraffin dressings has been shown schematically in fig.3. The real appearence of the fabric is shown in fig.4.

Fabrics of leno weave belong to this group of articles with the system warp-weft, in which the warp threads at least periodically are not parrallel, but they twist round one another, going from one side to the other. Thanks to this structure, the fabric, still characterized by small surface mass and small density of warp and weft - has a more stable structure, threads of warp and weft are fastened better, which results in a decreased possibility of threads displacement and smaller fraying of edges. This means that undesirable features of



3. Structure of leno weave

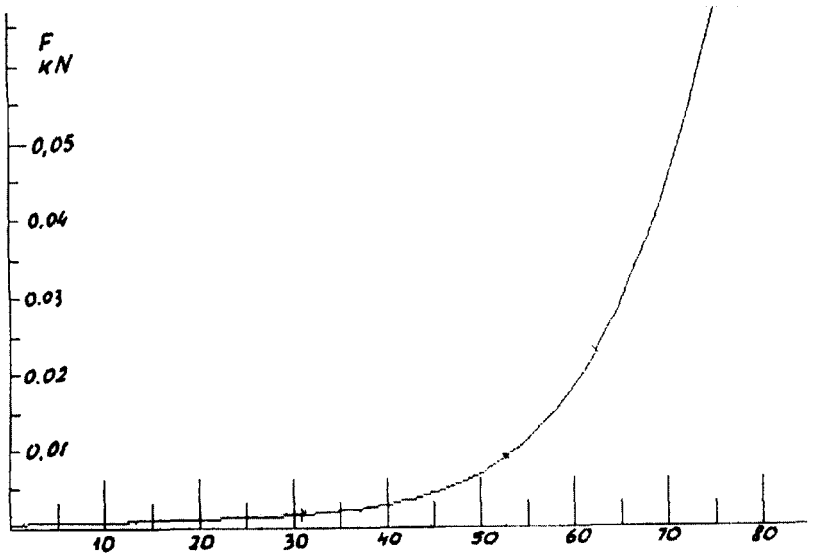


4. The real appearance of the fabric of leno weave

Table 1. Physico-mechanical parameters of fabrics used as dressing gauze and bandage.

No.	Parameter	Unit	Standard dressing gauze	Paraffin dressing and bandage	Elastic bandage	Testing method
1.	Surface mass	gm^{-2}	33	40 - 90	175	PN-ISO 3801 1993
2.	Linear density of yarn					
	warp	tex	20	20 – 40	52[1]	PN-P-04625 1998
	weft		20	20 – 40	40	
3.	Number of threads in 1 dm					
	warp	pcs	120	90 – 120	120	PN-P-04637 1980
	weft		75	80 – 110	165[2]	
4.	Breaking force not less than					
	warp	daN	10	10 – 22	27	PN-88/P-04626
	weft		6	6 – 16	29	
5.	Elongation					
	warp	%	-	11	94	PN-88/P-04626
	weft		-	20	27	
6.	Weave		plain	leno	leno	

[1] The warp threads consist of twofold cotton threads with a count 25 tex and of Lycra threads with a count 78 dtex.
[2] For weaving 100 pics per 10 cm.



5 Diagram of leno elastic bandage elongation as a function of Force

Table 2. Requirements of chemical purity for dressing gauze.

No.	Parameter	Index value		Testing method
		required	achieved	
		PN-79/P-82050		
1.	Water extract reaction pH	6.5 - 7.5	6.7	acc. to the provisions of Polish Pharmacol-ogy
2.	Chloride content %	< 0.0035	< 0.0035	
3.	Sulfate content %	< 0.01	< 0.01	
4.	Ash content %	< 1.2	0.15	
5.	Fat content %	< 0.4	0.16	
6.	Copper number of reducing substance content	< 1.2	0.2	
7.	Sinking time, s		4	
8.	Water absorption, ratio	< 10	6	
9.	Content of water-soluble substance %		0.2	
10.	Humidity %		5.6	

ordinary gauze of plain weave are eliminated Table 1 presents comparative physico-mechanical parameters of standard gauze and of fabric of leno weave used in paraffin dressings and bandage.

For elastic bandage the diagram (see Fig. 5) shows elongation of elastic leno fabric as a function of Force.

All textiles used for dressings must meet certain, defined parameters of chemical purity, which are given in table 2. This refers both to standard gauze and the gauze used for paraffin dressings.

Regulations concerning pharmaceutical agents and medical materials impose an obligation on the producer to carry out all necessary tests and present the results in the application. The required tests include:

- cellular toxicity,
- irritation,
- allergy,
- subacute toxicity,
- mutagenicity
- cancerogenicity and biodegradation (in some specific cases).

Table 3. Test results of paraffin dressings water extracts.

No.	Test type	Serial No. paraffin dressings		K
		Series 27.03	Series 04.04	
1.	pH reaction	6,22	6,32	5,86
2.	Electrical conductivity μs cm^{-1}	37,0	35,0	0,5
3.	Solid residue after vaporizing 200 ml of extract g/100cm^3	0,0077	0,0049	-
4.	Hemolytic action - % of hemolysis	0,15	0,30	-
5.	Cytotoxic action on bull's spermatozoons - proportional difference between the survival time of spermatozoons in the sample and control	10,0	12,83	-
6.	Survival time of spermatozoons in the sample min.	54	52,3	60
7.	Intradermal toxicity	no toxic action		
8.	Presence of febrific substances	no pyrogenic action		
9.	Absorption of water by the dressing %	14	17	-

All results are the average results of three extracts.

K: control - pH - redestilled water
- survival time of spermatozoons - 0,9 % NaCl

Allowable percentage of hemolysis 1%.

Allowable difference between the pattern of spermatozoons survival in the sample and control < 15%.

Sample series of paraffin dressings manufactured by Viscoplast SA from the fabric developed in the Institute of Textiles Architecture, were given for examination to the Department of Experimental Surgery and Biomaterials Testing of the Chair of Traumatic Surgery and Surgery of Hand of the Medical University of Wrocław and to the Clinic of Traumatic Surgery of the Medical University of Wrocław..

In the Department of Experimental Surgery and Biomaterials Testing of the Medical University in Wrocław the preliminary biological evaluation of the samples of new dressing materials was prepared. In accordance with the recomendations of the Pharmaceutical Agents and Medical Materials Registration Commission the following tests of water extracts were performed:

- laboratory measurements of pH, of electrical conductivity, and of solid residue after vaporizing 100 ml of the extract,
- examination of hemolytic action on human erythrocytes,
- examination of cytotoxic action on bull's spermatozoons,
- febrific substances testing,
- examination of local toxic action,
- examination of irritating action.

Test results of paraffin dressings water extracts are shown in table 3.

Biological examinations of paraffin dressings water extracts presented in table 3 show that paraffin dressings given for examination meet the basic requirements concerning bioconformity.

They showed that paraffin dressings are free from febrific substance (apyrogenic).

Tests of local toxic action of each water extract were performed on rabbits. The results show, that in 6 intradermal injections, only in one place there was a slight reddening of skin, of a diameter 1,5 mm. Thus it was found that water extracts of paraffin dressings of the above mentioned series do not cause local toxic action. They also do not cause any irritating action on the rabbit's skin.

On the basis of positive results of biological tests, clinical tests of paraffin dressings were carried out in the Clinic of Traumatic Surgery and Surgery of Hand of the Medical University in Wrocław. 60 samples were prepared and they were compared with paraffin dressings Jelonet produced by Smith + Nephew. In none of the samples, neither in tested ones nor in control ones, no allergic reaction, like itching or burning sensation, was found. There was also no reddening found under or near the dressing.

Tested dressings showed good clinical usability, especially in case of large wounds with skin defect.

Biological tests of paraffin dressings water extracts showed that the new paraffin dressings do not cause:

- hemolytic action on human erythrocytes,
- cytotoxic action on bull's spermatozoons,
- local toxic action,
- no febrific substances were found,
- they meet basic requirements of biological conformity,
- can be subject to further testing on animals.

Summing up, one should say that dressing materials for dressing skin, hypodermic and muscle tissue defects ought to be characterized by optimum protective and healing properties. Dressings should be impermeable for microorganisms, free from toxic, allergic and irritating action and they cannot cause pathologic reactions of tissues.

Bibliography

1 E Wilk, A Kluka, J Chodziński, 'Niektóre aspekty stosowania bawełnianych tkanin gazejskich w nowej generacji środków opatrunkowych, III int conf MEDTEX'99, Łódź Stowarzyszenie Włókienników Polskich, Polska Akademia Nauk 1999.

18. Anisotropic Fluid Transmission in Nonwoven Wound Dressings

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ABSTRACT

Many of the nonwoven structures used for absorbent wound dressing applications as well as other personal hygiene products exhibit anisotropic fluid transmission characteristics which, depending on the application, can markedly influence performance in use. Fibre orientation in such structures is believed to have a major influence on anisotropic fluid transmission and can be manipulated (as required) to engineer desirable fluid transport properties. Experimental results are presented which demonstrate the anisotropic fluid transmission properties of typical wound dressing structures. A new model of directional permeability is presented which takes into account the fibre orientation function of the structure and is capable of predicting the permeability in both the cross and machine directions of the fabric. A new method of measuring fluid transmission in multiple directions is also introduced.

1. INTRODUCTION

In practice, many nonwoven fabrics used in medical applications exhibit anisotropic fluid transmission characteristics, either in-plane or in the transverse plane of the fabric. This is apparent as differences in the liquid absorption rate measured in different directions in the fabric. Previously, such differences in absorbency have been ascribed to differences in the structure of the fabric (Adams and Rebenfeld, 1987).

Despite the importance of anisotropic in-plane fluid flows in nonwoven structures there have been relatively few published studies. Indeed, most of the existing models of either air permeability or liquid permeability established for textile fabrics, e.g., Kothari and Newton (1974), Dent (1976), Subramaniam *et. al* (1986), Shen (1996), Iberall (1950), are based on the assumption that nonwovens are isotropic structures.

While the capillary channels in highly porous nonwoven structures are probably very poorly defined it is common to model fluid transmission in such structures using classical capillary channel theory. An alternative approach relies on a consideration of the drag forces acting on the moving fluid due to contact with fibres in the structure. Happel (1959) modelled fluic transmission using this 'drag force' approach based on the assumption that fibres are oriented in specific types of unidirectional alignment in the fabric. With respect to nonwovens this is a gross assumption because in a real structure fibres are oriented in various directions as defined by a fibre orientation distribution.

2. IN-PLANE PERMEABILITY PREDICTIONS

2.1 Theoretical prediction of the in-plane permeability in nonwovens

A new model which takes account of the relationship between fibre orientation and the directional permeability of homogeneous nonwoven fabrics has recently been proposed. This allows prediction of the in-plane permeability and anisotropy of nonwovens (Mao and Russell, 1999). The model considers fabric structural parameters, such as fibre diameter, the fibre orientation distribution and porosity. Based on this model, the ratio of the directional permeability in the machine direction (MD) to the cross direction (CD) can be predicted. In fact, the permeability in any direction in the fabric can be predicted. The predictions from the new model have been compared with experimental results and appear to be in good agreement.

In order to simplify the calculation of permeability fibres aligned in the Z-direction are ignored, and the fluid flow is assumed to be laminar and in-plane. The radial directional permeability in the fabric plane, $k(\theta)$, which is a function of the flow direction θ, can be written as follows (Mao & Russell, 1999):

$$k(\theta) = -\frac{1}{32}\frac{\delta^2}{\phi}\left\{\frac{ST}{\sum_{\theta_i=0}^{\pi}\Omega(\theta_i)\left[T\cos^2(\theta-\theta_i)+S\sin^2(\theta-\theta_i)\right]}\right\} \qquad (2.3)$$

Where $T = [\ln\phi + \frac{1-\phi^2}{1+\phi^2}]$ and $S = [2\ln\phi - 4\phi + 3 + \phi^2]$

In equation (2.3):

θ = flow direction,

θ_i = fibre orientation in each direction of the fabric plane,

ϕ = volume fraction of the solid material,

$k(\theta)$ = directional permeability of the fabric,

δ = fibre diameter,

$\Omega(\theta)$ = fibre orientation distribution function.

2.2 Theoretical prediction of the in-plane anisotropy of permeability in nonwovens

If we assume $\theta = 0$ when fibres are oriented in the machine direction, the permeability in this direction will be $k(\theta)|_{\theta=0}$. The permeability in the direction $\theta = \frac{\pi}{2}$, (where fibres are oriented in the cross direction), will be $k(\theta)|_{\theta=\frac{\pi}{2}}$. If we assume that all the differences in the liquid transport velocity are due to differences in the directional permeability, then the anisotropy of liquid absorption in the fabric can be expressed as the ratio of the two permeabilities as follows:

$$\alpha = \frac{k_r(\theta)|_{\theta=0}}{k_r(\theta)|_{\theta=\frac{\pi}{2}}} = \frac{\left\{\sum_{\theta_i=0}^{\pi} \Omega(\theta_i)[T\cos^2\theta_i + S\sin^2\theta_i]\right\}}{\left\{\sum_{\theta_i=0}^{\pi} \Omega(\theta_i)[T\sin^2\theta_i + S\cos^2\theta_i]\right\}} \quad (2.4)$$

Where $T = [\ln\phi + \frac{1-\phi^2}{1+\phi^2}]$, $S = [2\ln\phi - 4\phi + 3 + \phi^2]$

3. FLUID TRANSMISSION IN WOUND DRESSING FABRICS

3.1 Experimental results

To determine the anisotropy experimentally, two commercial nonwoven wound dressings were evaluated by the standard strip test (DIN53924, BS3424 method 21). Liquid uptake tests on the dressing structures revealed that dressing 2 consisting of cellulosic, non gelling fibres had the highest absorption capacity and the highest porosity. Dressing 1 containing gel-forming fibres (Alginate) exhibited the lowest absorption capacity (probably due to gel blocking) and the lowes porosity (see Tables I and II).

Clearly, fabric porosity and fibre diameter are fundamentally important in predicting the permeability of nonwovens (see equation (2.3)) and because nonwovens are compressible, porosity varies with fabric thickness. For the two dressing structures, fabric thickness and porosity with and without compression were measured (see Table II). It was decided that fabric porosity (obtained with no compression) would be used in the prediction of permeability since the strip test results were obtained under conditions of zero compression.

Dressing	Fibre Type	Fibre Density (g/cm^3)	Fibre Diameter (μm)
1	Calcium Alginate	1.75	12
2	Cellulosic	1.49	16

Table I Fabric absorbency and fibre parameters

Dressing	Fabric Thickness (mm)		Fabric Density (mg/cm^3)	Fabric Porosity		Water Absorption Capacity of Fabric	
				Calculated Porosity From Dry Fabric	Calculated Porosity From Saturated Fabric	(g/g)	(mg/cm^2)
1	No compression	0.80	0.136	92.21	87.61%	7.07	154.90
	Pressure = 5 (lbs/psi)	0.415	0.263	84.97			
2	No compression	2.50	0.048	96.78	98.22%	55.30	211.80
	Pressure = 5 (lbs/psi)	0.535	0.224	84.97			

Table II Fabric porosity and fabric absorbency

3.2 Assessment of the vertical wicking height and the anisotropy of absorbency

In Figures 1, 2 and table III, the fluid rise height in the fabric vs. time obtained in the vertica strip tests are presented for the two dressings. It is noticed that both the wicking height and th maximum rise height from the vertical strip test in the cross direction (CD) are generally lowe than in the machine direction (MD). It is also noted that the absorption rate in the cross directio was generally lower than in the machine direction (MD). This clearly shows the anisotropy o liquid absorption in the two dressings. Experimental work has established that this apparentl corresponds to the anisotropy of the fibre orientation in both the machine and cross direction (MD and CD). The results of the anisotropy tests indicate that dressing 2 has a greater anisotrop (1.571) than that of dressing 1 (1.208) while dressing 1 absorbed liquid much quicker tha dressing 2. It is therefore possible to conclude that the structure of dressing 2 is more anisotropi than the structure of dressing 1.

Dressing	Fibre Type	Vertical test h_{max} (cm)		Anisotropy of absorption (Vertical Strip test)
		CD	MD	
		h_{max}^{CD}	h_{max}^{MD}	$\frac{h_{max}^{MD}}{h_{max}^{CD}}$
1	Calcium Alginate	4.8	5.8	1.208
2	Cellulosic	2.1	3.3	1.571

Table III Experimental results of permeability and anisotropy

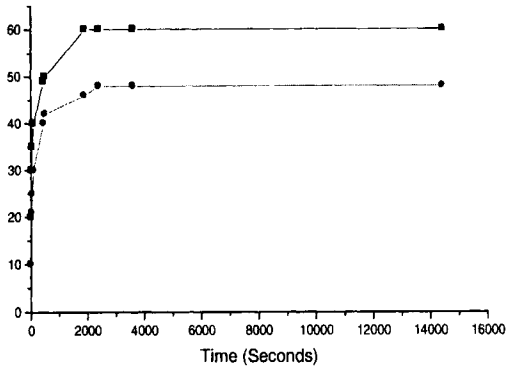

Figure1 Vertical Strip test of water wicking of dressing 1

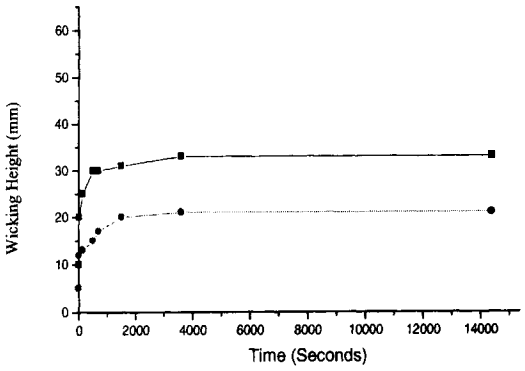

Figure 2 Vertical Strip test of water wicking of dressing 2

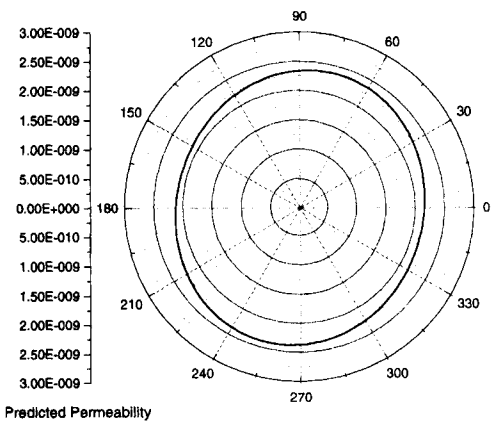

Figure 3 Predicted permeability of dressing 1

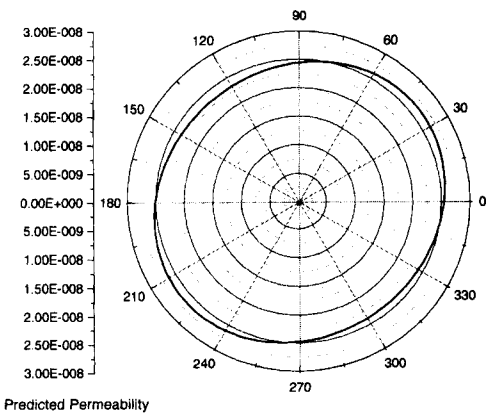

Figure 4 Predicted permeability of dressing 2

4. FIBRE ORIENTATION DISTRIBUTION AND THE PREDICTED ANISOTROPY OF PERMEABILITIY

The predicted directional permeabilities of the fabrics according to equation (2.3) are plotted in figures 3 and 4. The fibre orientation distribution of each dressing was obtained using image analysis and the results substituted into the equation.

The predicted anisotropies of permeability of dressings 1 and 2 are 1.123 and 1.126 respectively (see Table IV). The predicted permeability can be employed in Darcy's law to explain the dynamic fluid transmission but this is beyond the scope of this paper.

It may also be noted from figures 3 and 4 that both the maximum and minimum directional permeabilities are obtained neither in the true cross direction nor in the machine direction. Rather, the maximum and minimum directional permeabilities correspond to the positions of the maximum and minimum peaks in the fibre orientation distributions for each dressing structure. It is found that the anisotropy of fibre orientation in each of the dressing structures is correspondent with the anisotropy of directional permeability. The fibre orientation distribution would appear to play a key role in determining directional permeability.

Dressing	Anisotropy of Fibre Orientation	Predicted Permeability					
		Permeability ($*10^{-10}$)				Anisotropy	
		K_{MAX}	K_{MIN}	k_{MD}	k_{CD}	$\frac{k_{MD}}{k_{CD}}$	$\frac{k_{MAX}}{k_{MIN}}$
1	1.239	1.163	1.036	1.151	1.046	1.100	1.123
2	0.966	12.958	11.506	12.351	12.031	1.027	1.126

Table IV Predicted results of permeability and anisotropy

5. DYNAMIC MEASUREMENT OF ABSORPTION AND ANISOTROPY

Conventionally, strip tests are carried out in the 'true' machine direction and also perpendicular to this in the 'true' cross direction. This approach does not necessarily give a comprehensive picture of the fabric anisotropy and measurements cannot be made in both directions simultaneously on one sample. Numerous methods have been devised for permitting measurements of absorbency to be made in more than one direction of the fabric (Adams and Rebenfeld (1987), Miller and Tymokin (1984), Kawase et al (1988)) but they are limited by cost and by practical constraints in their use. A patented device developed by the authors at the University of Leeds uses a computer integrated approach employing capacitance to measure fluid transmission in fabrics in at least eight different directions simultaneously (see Figure 5). This method allows dynamic measurement of total wicking and absorbency in multiple directions in the fabric as well as providing combined results for total absorbency and wicking. This instrumental method of measurement is providing important new insights into the directional fluid transmission of medical and hygiene fabrics.

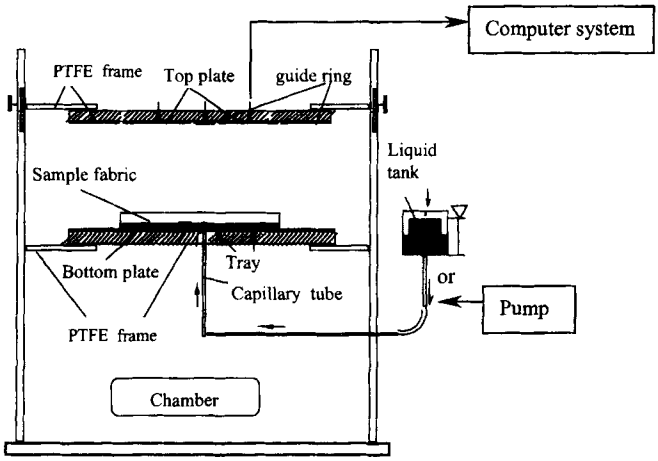

Figure 5 Capacitance system for measurement of liquid transmission in fabrics

6. CONCLUSIONS

In this approach, the anisotropy of the in-plane directional permeability of nonwoven dressings has been investigated. Based on a new model of directional permeability and the fibre orientation distribution of the sample fabric, the directional permeability in the machine and cross directions can be predicted. The main findings may be summarised as follows:

(i). It has been shown that some commercial wound dressing structures exhibit marked anisotropy of liquid absorption.

(ii). A new model (Mao and Russell, 1999) of the relationship between fibre orientation and the directional permeability in homogeneous nonwoven fabrics has been adopted to predict the in-plane permeability and anisotropy of dressing fabrics.

(iii). The fibre orientation distribution in such structures is believed to have a major influence on anisotropic fluid transmission. This is shown in both the predicted results and the anisotropy of fibre orientation.

(iv). Both the directional permeability and the anisotropy of permeability are determined by the fabric porosity, fibre diameter and the fibre orientation distribution. The fibre diameter is also of major importance in determining the permeability of nonwoven structures.

(v) An alternative instrumental method of measuring the wicking and fluid absorption in nonwoven fabrics has been devised that allows dynamic measurements in multiple directions simultaneously.

REFERENCES

1 K L Adams and L Rebenfeld, In-plane flow of fluids in fabrics: structure/flo characterisation, *Text. Res. J.*, 1987, 57, 647.

2 R E Collins, *Flow of Fluids through Porous Materials*, Reinhold Publishing Corporatio New York, 1961.

3 R W Dent, The air permeability of nonwoven fabrics, *J. Text. Inst.*, 1976, 67, 220-224.

4 J Happel, Viscous flow relative to arrays of cylinders, *AIChEJ*, 1959, 5, 174.

5 Iberall, A. S., Permeability of glass wool and other highly porous media, *J. Res. Nat. Bu Stand.*, 1950, 45, p398.

6 T Kawase, S Sekoguchi, T Fuju and M Minagawa, Spreading of liquids in textile assemblies, Part 3: application of an image analyser system to capillary spreading of liquids, *Text. Res. J.*, 1988, 58, 306.

7 V. K. Kothari, and A. Newton, The air permeability of nonwoven fabrics, *J. Text. Inst.*, 197 65, 525.

8 N Mao and S J Russell, Directional permeability of homogeneous anisotropic fibrou material, Part 1, submitted to *J. Text. Inst,* 1999.

9 B Miller and I Tymokin, Spontaneous Transplanar uptake of liquids by fabrics, *Text. Res.* . 1984, 54, 706.

10 Shen, X., *An application of needle-punched nonwovens in the press casting of concret* Ph.D. Thesis, University of Leeds, 1996.

11 E M Sparrow, and A L Loeffler, Longitudinal laminar flow between cylinders arranged i regular array, *AIChEJ*, 1959, 5, 325-330.

12 V Subramaniam, M. Madhnsoothanan, and L R Debnath, Air permeability of blend nonwoven fabrics, *Text. Res. J.*, 1986, 56, 677.

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19. Advanced Materials for Wound Dressings: Biofunctional Mixed Carbohydrate Polymers

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ABSTRACT

Polysaccharide-based dressings have increasingly become viable alternatives to biologically incompatible and often problematic cotton or viscose gauzes traditionally used for wound dressings. Abundant availability of alginates and their relative ease of solubility in particular have been instrumental in their development into fibres and lately their application as vehicles for delivering drugs. This paper reports on spinning efficiency of various alginate grades (i.e. differing mannuronic/guluronic acid ratios) in a laboratory based extrusion system and explores the effect of proportional inclusion of a second polysaccharide compound on tensile properties of the resulting fibres.

Branan ferulate has been focused on as the second polysaccharide, since this has gel forming capabilities currently being harnessed in Sterigel® which is a wound healing formulation containing cross linked branan ferulate.

Introduction

The concept of wound or rupture in otherwise delicate skin and tissues below it is neither technical nor alien to man. From early days, in pursuit of survival, man has had to inflict injury on his prey and fellow human beings or indeed suffer as a victim. However, wounds in modern terms are much more varied and reflective of our evolved way of life. Wounds and injuries today can result from a range of potential hazards including fire, natural disasters, transport accidents, diseases, operations, cosmetic surgery, sports, self inflicted injuries and so on.

High expectations of recovery and impeccable reparation demands with minimal discomfort to the patients have in the last decade, in particular, led to some novel and daring wound management practices. New fibrous and

wound dressing media have been developed to encourage wound occlusion, exudate transport and drug dispensation on demand with much reduced distress to the patient. In this paper one such system where different alginate grades are used, the efficiency of alginate fibres is examined to evaluate their ability to carry a second polysaccharide polymer, which is already marketed as a hydrogel wound dressing (Sterigel®) for the treatment of necrotic and sloughy wounds particularly venous and arterial leg ulcers and pressure sores. A laboratory based extrusion unit has been specifically built and progressively developed to carry out these experiments.

Alginate Fibres

Consistency in texture and characteristic viscosity in marine algae or seaweed has been known as far back as 1883 and several early patents were granted for their extraction, physio-chemical properties and their industrial applications. Discovery of alginic acid later on and its treatment with alkaline bases led to a variety of products used as stabilisers, thickening agents, sizing and jelling compounds in a range of industries. Between 1912 and 1940, the Germans, Japanese and the British have acquired various patents on the extrusion of alginates into insoluble fibres.

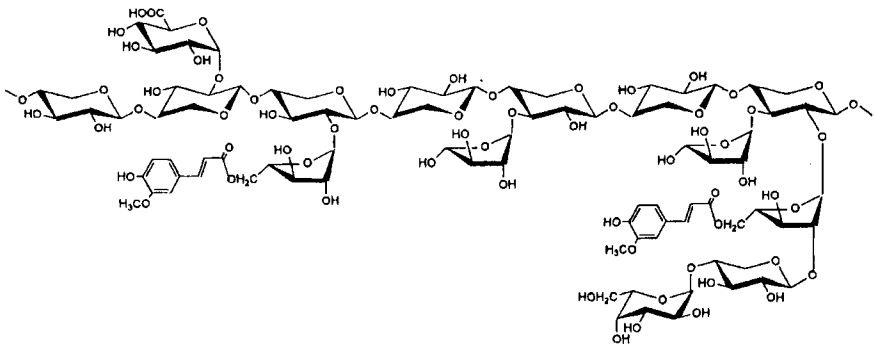
Seaweed alginate and hence the insoluble fibre or calcium alginate is essentially a copolymer made up of two monomeric acids, D-mannuronic (M) and L-guluronic (G). The relative proportion of the M and G monomers in fibre form in part determines fibre ultimate strength and moisture absorbency. High M unit content is usually related to greater uptake of moisture and hence weaker fibre. Calcium alginate fibres with various proportions of M and G are commercially available.

The fibre formation process is simple in operation and is essentially based on exchange of sodium ions (Na^{+}) present in the sodium alginate dope and calcium ions (Ca^{+2}) present in the coagulating calcium chloride bath. The calcium alginate fibre emerging from the coagulation bath is then washed, drawn and dried before being wound up.

Branan Ferulate

Branan ferulate is a polysaccharide or carbohydrate polymer extracted from corn bran. It is composed of L-arabinose, D-galactose, D-glucose, D-

glucuronic acid and D-xylose monomer units. Its general chemical structure is shown below.



In cross-linked, gel form branan ferulate is currently manufactured by SSL International plc and commercially marketed as Sterigel®. The preparation has special texture, water affinity and water donation properties. It is water "soluble" and its inclusion in alginate fibres would provide instantaneous as well as localised dispensation within the moist wound environment. Branan ferulate itself may infiltrate the biological activities in the body and hence accelerate the wound healing process.

Extrusion System and Materials

A mini-extruder based on wet extrusion principles has been designed and built in the laboratory. The extrusion unit, as shown in Figure 1, consists of a surgical syringe and needle, fibre coagulation and water baths, glass guide rollers, and a motorised take up system. A stepper motor geared to the piston inside the syringe controls the dope delivery rate.

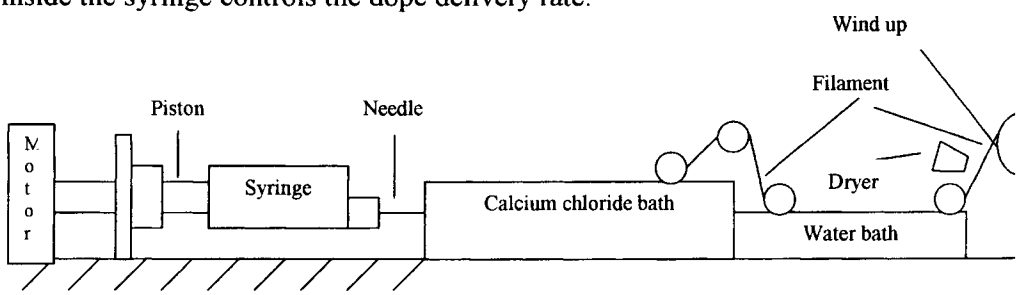


Figure 1: The Mini-extruder

The forward movement of the piston pushes the alginate solution through the needle and into the coagulating bath where sodium/calcium ion exchanges take place and single calcium alginate filament is generated. The filament is subsequently guided into the water bath and blow-dried prior to winding up.

Eight sodium alginate grades were sourced from three different suppliers. The manufacturers' names and polymer details are given in Table 1.

Table 1 Details of Experimental Polymers

	Company	Sample code and number
Alginates	Pronova Biopolymer	Protanal LF 10/60 (SLP 2975)
	Snap Natural & Alginate products Ltd.	FG (076998) FMP (076898) LVP (076798)
	NutraSweet Kelco	Manucol DH (1039) Manucol DM (1040) Manucol GHB (1012) Manucol DMB (1018)

Using all the alginates, initially a range of filaments were produced and the influence of the following variables on ultimate fibre properties were determined: sodium alginate dope concentration, calcium chloride bath concentration, dope delivery rate, take up speed, and needle gauge size.

The best performing alginates, with respect to their consistency in strength and extensibility, were subsequently selected to receive the branan ferulate. Increasing proportions of the branan ferulate were blended into the alginate dopes before extruding into the calcium chloride bath. The resulting filaments were washed, dried and their tensile properties compared to those of parent or unfilled filaments. Optical microscopy was later used to examine the filaments in cross and longitudinal sections.

Results

The investigations revealed that the delivery rate of 1.35mlmin^{-1} produced a steady flow of polymer allowing sufficient time for coagulation to occur. Optimum dope concentration of 5% gave viscosities in the range of

$2.48X10^3$ to $8.3X10^3$ cp with reasonably good fibrous properties. The calcium chloride concentration of 5% was the lowest concentration investigated and provided adequate coagulation so long as the bath containing the solution was no shorter than 1m in length. Needles of various gauge sizes (e.g. 20 to 27 equivalent to cross-sectional area of 0.125 to 0.636 mm^2) were used. The finer needles caused intermittent breakage in the spun filaments and the coarsest needle yielded a dope sheet that failed to convert fully the sodium component into calcium thus drastically affecting fibre strength. The intermediate gauge size of 25 or 0.2 mm^2 produced the best results. Winding up speeds in excess of 20 $mmin^{-1}$ achieved progressively better filaments with improved tensile properties.

Preliminary trials showed that all alginate grades mixed adequately with branan ferulate and showed little difference between the grades. However, the DM and GHB grades were much too viscous and did not spin as easily as the FMP and FG grades. The DH grade, as will be shown later, proved superior in both dry and wet state and was therefore chosen to carry the branan ferulate. However, to ascertain the range and scope of this feasibility four other alginates were loaded up to 75% with branan ferulate and their subsequent properties compared. Tables 2 shows the effect of proportional addition of branan ferulate to Manaucol DH and lists the tensile properties of the corresponding fibres.

Inclusion of up to 18% branan ferulate into the spinning dope results in fibres with tenacities and extensibilities similar to unfilled fibres (Table 2). Increasing the branan ferulate content up to 50% does not result in appreciable change in tensile properties but the resulting fibres become increasingly sticky causing fibre/fibre and fibre/bobbin adhesion. A branan ferulate content of greater than 50% increases spinning dope viscosity and reduces extrusion efficiency. However, under these circumstances fibres are still extrudable but display a marked drop in tensile properties and substantial stickiness. Higher dope viscosities also result in up to four-fold increase in linear densities.

Table 3 illustrates the effect of up to 75% loading of branan ferulate on different alginate grades and compares their resulting properties with the unfilled alginate filaments.

Table 2 Properties of Alginate/Branan Ferulate Experimental Fibres

Branan Ferulate (%) of total solid content	Winding speed (m/min)	Linear Density (tex)	Breaking Force (cN)	Tenacity (cN/tex)	S.D (cN)	Extension (%)	S.D (%)
0.0	22.76	4.3	35.30	8.21	3.14	16.06	1.86
	28.63	4.0	29.12	7.28	4.52	13.79	4.22
	29.37	4.3	24.98	6.25	6.57	12.61	6.16
	31.57	3.3	18.38	5.57	9.93	14.32	9.34
	34.51	3.3	19.44	5.89	7.60	16.01	6.14
	42.58	2.5	18.62	7.45	0.82	11.26	0.43
4.5	22.76	4.0	39.48	9.87	5.68	16.39	0.87
	27.17	4.9	32.60	6.65	3.24	16.06	0.89
	28.63	4.0	28.04	7.01	4.48	11.19	3.29
	29.37		31.30		2.29	14.74	1.74
	30.84		29.32		3.15	13.21	1.21
	31.57	4.5	26.90	5.98	3.07	13.52	2.86
	34.51		26.48		3.99	15.22	1.45
	42.58	2.6	23.30	8.96	0.78	11.06	0.87
	54.33		20.28		1.03	10.97	0.78
	47.72	2.6	12.32	4.74	3.72	8.82	1.60
10.7	22.76	4.4	38.91	8.84	7.14	14.35	1.83
	27.17	4.2	33.78	8.04	6.44	13.52	3.14
	28.63		33.26		2.46	15.78	2.32
	29.37		33.16		2.63	12.65	3.15
	30.84		33.10		9.57	11.05	2.03
	31.57	3.9	27.59	7.07	3.89	12.10	2.19
	34.51		22.60		2.81	14.77	1.99
	42.58		19.22		5.45	11.66	3.93
	54.33	2.7	15.91	5.89	3.79	8.82	1.37
18	22.76	5	32.96	6.59	3.47	15.94	2.11
	27.17	4.8	24.90	5.19	6.80	13.20	3.22
	28.63		25.22		1.86	15.28	1.46
	29.37		23.48		1.90	13.70	1.54
	30.84	5.2	27.44	5.28	2.12	14.84	1.37
	31.57	4.2	21.24	5.06	2.82	13.69	1.69
	34.51	3.6	21.64	6.01	3.63	121.78	3.18
	42.58	2.8	21.58	7.71	2.03	15.22	2.48
32.6	27.17		26.44		3.73	12.62	1.53
	29.37	12.3	23.56	1.92	5.10	8.03	3.33
	31.57		31.78		4.22	11.73	0.74
	34.51		30.04		7.14	8.96	0.78
	34.0	4.3	30.62	7.12	5.05	9.93	3.49
50	22.76	14.2	35.36	2.49	5.10	12.99	2.20
	27.17	14.5	28.85	1.99	3.92	10.64	1.91
	28.63		21.68		7.84	8.22	3.47
	30.84	14.5	21.78	1.50	5.53	8.51	2.70
	31.57		27.12		17.20	8.78	3.57
	34.51		19.17		2.72	7.73	2.35
	42.58	10.0	4.68	0.47	0.25	4.48	1.37
66	22.76	13.2	44.72	3.39	9.81	13.04	1.71
	27.17	15.5	51.89	3.35	12.57	15.12	2.82
	28.63	14.5	53.67	3.70	12.70	13.86	2.01
	29.37	16.9	32.82	1.94	11.89	11.83	2.73
	31.57	15.3	51.77	3.38	9.41	13.94	3.40
75	22.76	17.4	43.36	2.49	8.90	15.39	5.23

Table 3 Effect of 75% loading on alginate grades in dry and wet conditions

Branan Ferulate (%) of total solid content	Sample: Alginate Code & Winding speed ($mmin^{-1}$)	Linear Density(tex)	Breaking Force (cN)	Tenacity ($cNtex^{-1}$)	Elongation (%)
0	DH(22.76)	4.3	35.30 (14.42)	8.21 (3.35)	16.06 (48.63)
75	DH(22.76)	17.4	43.36 (5.98)	2.49 (0.34)	15.39 (19.30)
0	DM(22.76)	~4.3	37.34 (1.70)	8.68 (2.72)	24.35 (95.39)
75	DM(22.76)	~17.4	25.56 (4.62)	1.47 (0.27)	11.11 (31.34)
0	GHB(22.76)	~4.3	53.10 (13.66)	12.35 (3.64)	15.71 (59.25)
75	GHB(22.76)	~17.4	33.54 (4.72)	2.04 (0.27)	24.78 (20.00)
0	FMP(22.76)	~4.3	21.96 (9.40)	5.11 (2.19)	12.78 (28.61)
75	FMP(22.76)	~17.4	30.20 (4.54)	1.74 (0.26)	12.92 (11.29)
0	FG(22.76)	~4.3	41.86 (8.70)	9.73 (3.88)	17.96 (83.76)
75	FG(22.76)	~17.4	28.88 (3.38)	1.66 (0.19)	16.17 (9.24)

The shaded figures refer to tests carried out in wet condition.

The figures in shaded background correspond to wet state tensile properties. All unfilled or branan ferulate free samples are severely affected by water resulting in drastic drops in tenacities and increases in extensibilities. The branan ferulate/alginate filaments show even further drop in tenacities whilst wet, but considerably restrict filament elongation compared to unfilled alginates. Under all conditions the fibrous integrity is maintained.

The DH and FMP, in dry state, are the only two grades that show increase in breaking force when loaded with 75% branan ferulate. However, only the DH grade, in wet condition, shows the highest breaking force and hence the highest tenacity.

Visual appearance of alginate filaments containing increasing proportions of branan ferulate changes from dirty white to pale yellow and eventually to

gold. Their cross sectional shapes also change with increasing take up speeds and drying efficiency. Figures 2 and 3 show the transformation in cross sectional shape with improvements in the drying technique under specific spinning conditions.

Figure 2, rod shape cross sections prior to modifications.

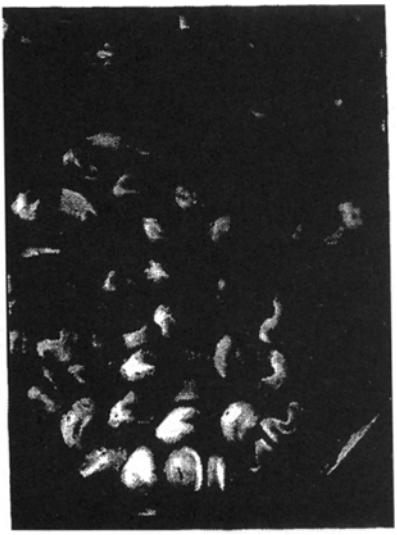


Figure 3, near circular cross sections after modifications.

Discussion and Conclusions

Polysaccharides are naturally occurring macromolecules derived from plants or animals. They are hydrophilic in character, biologically compatible and are therefore potentially suitable for woundcare applications. Branan ferulate, an extract from corn bran, is one such polymer whose spinnability into fibres has been investigated in this study. Although it can not be spun into fibres in its pure or unaided state, the work has shown that it can easily be blended and carried by an alginate-based fibre. In fact proportional addition of branan ferulate to appropriately selected alginates could reach as much as 75% branan ferulate without affecting fibrous characteristics. However, since branan ferulate is inherently sticky, this will gradually be reflected in the resulting fibres with increasing addition of branan ferulate. Depending on the specific method of fabric conversion and area of

application i.e. nonwoven, knitted or woven, the branan ferulate content could be adjusted to achieve desired tensile and other mechanical properties. The cross sectional dimensions of these fibres are shown to be independent of branan ferulate content. But they may be regulated with respect to the type of drying unit employed and spinning conditions adopted

The mini-extruder, designed and built in the laboratory, has enabled fundamental investigation into alginate fibres containing branan ferulate and has allowed exploration of the range and scope of versatility of these fibres.

Based on these studies a large scale wet extruder is now in place and studies carried out on this equipment will be reported at a later stage.

Acknowledgements

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References

1. Textile Fibres, 5th Edition, H.R. Mauersberger, Wiley, Chichester, 1947.
2. Burn wound coverings-A Review, G.B. Park, Biomat., Med.,DEV.,ART. ORG.,6(1), 1-35 (1978).
3. Novel Polysaccharide Fibres for Advanced Wound Dressings, Y.Qin, C. Agboh, X. Wang and D.K. Gilding, Medical Textiles International Conference, Bolton, UK, 1996.
4. Extracts from confidential reports submitted to SSL International, 1998/1999.
5. New Fibres, T. Hongu and G. O. Phillips, Ellis Horwood, Chichester, 1990.
6. The chemical structure of a novel polysaccharide, Sterigel, suitable as a wound management aid, J.F. Kennedy, P. MeMethacanon, L.L. Lloyd, M. Paterson and C.J. Knill, 6th European conference on advances in wound management, Macmillan Magazines Ltd., London, 1997, pp 141-147.
7. Sustained release alginate fibre and process for the preparation thereof, United States Patent No. 5,690,955, November 1997.

20. Fibrous Scaffolds for Tissue Culturing

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INTRODUCTION

Tissue engineering brings together biological and engineering disciplines in order to culture viable human tissues outside the body. The purpose is to provide surgical implants which are appropriate for replacement/repair of damaged sites in the body. These are needed because the body is not always able to repair itself and in these cases an implant of some form often becomes necessary to restore function (1). Tissue engineering provides surgeons with the possibility of implanting living tissue which will eventually integrate fully with the patients own tissue.

A key part of tissue engineering is the scaffold which supports the tissue forming cells. The scaffold needs to fulfil many requirements, it not only gives the overall shape and structure of the implant but also influences the environment in which the cells grow. For example, the scaffold is important in determining the distribution of the cells and the flow of nutrients. Fibrous materials are particularly suitable for the fabrication of scaffolds as they can be designed to have both large internal surface areas and high porosity (2,3,4). Scaffolds may be composed of bioresorbable fibres, so that eventually only tissue remains at the implant site.

The Tissue Engineering Process

The tissue engineering process begins with a scaffold and a supply of cells. The cells may be the patient's own cells, a donor's or taken from a cell bank. They are then seeded into a prepared scaffold. The cells attach themselves to the scaffold and are cultured within a mini bio-reactor. A supply of tissue culture media provides nutrients for the cells and removes waste products. During culturing, which may last several weeks, the cells increase their numbers and lay down the extra-cellular matrix to form a neo-tissue. If bioresorbable fibres are used then these will start to degrade. At the end of culturing the tissue engineered construct may require preservation and storage before it is used as an implant.

THE PROPERTIES REQUIRED OF FIBROUS SCAFFOLDS

The scaffold performs numerous important functions which all need to be taken into account and adjusted according the requirements of a specific tissue type.

1. The scaffold defines the overall size and shape of the implant
2. Provides the correct internal structure which allows cells to enter the scaffold, attach and grow.
3. Provides appropriate surfaces for the cells to attach onto.
4. The scaffold may also control the orientation of the cells and matrix.
5. Allows ingress of nutrients at rates required by the cells.
6. Biocompatible and safe.
7. The fibres may be bioresorbable so that eventually all the scaffold is replaced by living tissue.
8. Compatible with the bio-reactor system.
9. Mechanical properties sufficient to support the developing tissue

10. Structural reinforcement of the neo-tissue may also be required during implantation or to assist the initial function of the tissue.

Fibrous Scaffold Materials

The requirement is for fibre forming polymers which must be biocompatible and preferably bioresorbable. These may be naturally derived or synthetic. The most important synthetic group are the resorbable polyesters, especially poly (glycolic acid) and poly (lactic acid). They can be used as either homopolymers or as various copolymers. The polymers have an established history of use, either as sutures or as other surgical devices (5-7). Degradation is by hydrolysis followed by metabolism of the residues. The time taken for these polymers to resorb is dependant on many variables and ranges from a few weeks to many months (3,8).

FIBROUS SCAFFOLD STRUCTURES

One method for categorising tissue engineered implants is by the structural complexity of the scaffold which is used, as represented in fig. 1.

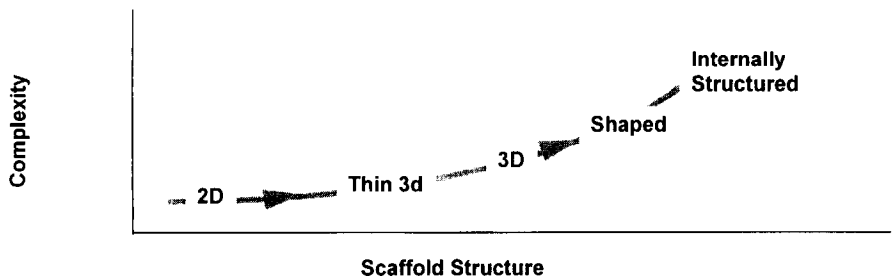

Fig 1 Complexity of tissue engineering linked to scaffold structure

The 2D or 'thin 3D' scaffolds are very appropriate for culturing tissue engineered skin (9). Culturing dermal fibroblasts on a thin matrix reduces some of the complexities of tissue engineering: for example the challenge of maintaining a supply of nutrients to the centre is reduced

Thin 3D Scaffolds : Dermagraft

Dermagraft ™ is a tissue engineered skin cultured on a 'thin 3D' scaffold. It is being commercialised through a joint venture between Advanced tissue Sciences (USA) and Smith and Nephew. It is indicated for use on diabetic foot ulcers. These wounds are difficult to heal and can often lead to serious complications (10). In this case the scaffold is a crocheted mesh (Vicryl ™ Ethicon, USA) which is produced from multifilament yarn, a 90/10 co-polymer of poly-glycolic and poly-lactic acid. Human dermal fibroblasts are seeded onto this scaffold to which they attach (fig.2). During culturing the cells proliferate and secrete proteins characteristic of human dermis. The result is a human dermal tissue containing metabolically active cells and a dermal matrix (9).

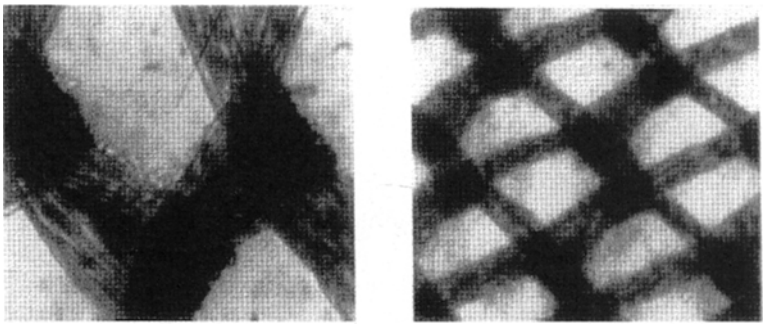

Fig 2. Micrographs of Dermagraft [TM] showing the Dermal Matrix on the Scaffold

3D Scaffolds: Cartilage in the Knee

In the knee there are two types of cartilage:

1. Articular Cartilage: The joint surfaces of the femoral condyles and the tibial plateau are each covered with a layer of articular cartilage up to 5 mm thick.
2. Meniscal Cartilage: The menisci, which lie between the articular surfaces, are composed of fibrocartilage. They are crescent shaped structures with a triangular cross section.The extra cellular matrix in this tissue contains collagen fibres which are aligned both radially and circumferentially.

Both types of cartilage have very limited ability to self repair and damage due to trauma or disease tends to lead to progressive deterioration of the joint (11). To produce surgical implants of tissue engineered cartilage requires a scaffold with a significant 3D structure. Needled felts are a solution for this.

NEEDLE FELT SCAFFOLDS

Needled felts are an appropriate route to providing 3D fibrous scaffolds for tissue engineering (2, 4, 14). The advantages are:

- A very wide range of felt thickness' and densities can be achieved.
- The process can be applied to a wide range of fibres.
- The process can be operated at small scale :
    - Intensive process monitoring required to attain high uniformity
    - Large volumes not required as many implants per square meter.
    - The cost of the resorbable fibre is very high.

The key design factors are: fibre type, overall dimensions, inter-fibre spacing and fibre orientation. For a given yarn the inter-fibre spacing and internal surface area are both functions of bulk density.

Processing

The processing route for preparation of a needled felt scaffold is shown in fig. 3.
The main considerations in the preparation of the felt are:

1. Avoid degradation of the polymer:
    - Limit exposure of the material to ambient moisture.
    - Re-dry the material before packaging and storage.
    - Use desiccated packaging

2. Process hygiene - i.e. avoid contamination of the materials from the:
    - Operators
    - Equipment
    - Environment
3. Consistency and Uniformity:
    - Material conforms to tight tolerances.
    - Minimise wastage of high value yarns and fabric.

The initial processing stages lead to the preparation of the staple fibre. This is then passed repeatedly through a specially set, fine wire card with the aim of building up uniformity. The basis weight of the carded fleece is closely controlled and includes appropriate allowances for the anticipated dimensional changes on needling. The fleece is transferred to the needling loom, taking care to avoid distortion and then needled to progressively bring the thickness and density within tight tolerances. The felt is then scoured in solvent to remove the spin finish and any processing contamination. High purity solvents are used to avoid introducing any additional contaminants. This is followed by a vacuum annealing stage which has multiple functions: it removes residual solvent, thoroughly dries the felt, removes low molecular weight polymer and stabilises the felt.

The felt is then cut into the shapes required for the bioreactors. It is important that felt uniformity is high so that each disc conforms to the specification for thickness and density.

The sterilisation of these polymers is fraught with difficulties (12). Ethylene oxide sterilisation is the method commonly used to avoid the degradation resulting from radiation techniques (13). Ethylene oxide is however a warm moist process and has been observed to cause some degradation of the fibres. Also the fibres, especially PGA, have a very strong affinity for ethylene oxide gas requiring thorough vacuum degassing to reduce residues to negligible levels.

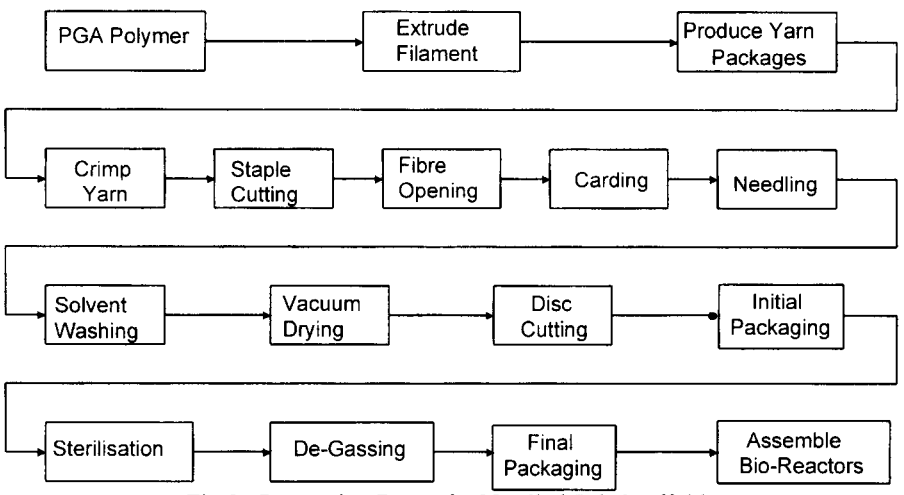

Fig 3 Processing Route for Needled Felt Scaffolds

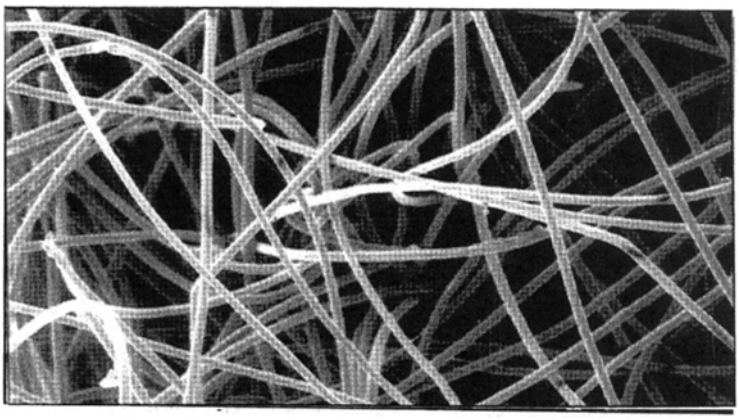

Fig 4. Electron Micrograph of a PGA felt Scaffold

Structural Properties of Needled Felt Scaffolds

The needled felt is essentially a randomised entanglement of filaments. A typical structure is shown in fig 4

A more detailed analysis of the structural properties can be obtained by sectioning a resin embedded sample and carrying out image analysis. The size and spacing of the filaments may thus be measured. It is also possible to determine the orientation of the filaments from the relative dimensions of the major and minor axis of the elliptical sections. An example of the frequency distribution of fibre spacing is shown in fig 5.

The structure of the felt and relationships between key variables that are important to tissue engineering can also be studied by mathematical modelling. An assumption is made that the felt structure is uniformly random in all dimensions and the results show close agreement with the data from image analysis. The example in Fig 6. shows the effect of variations in the bulk density of a PGA felt.

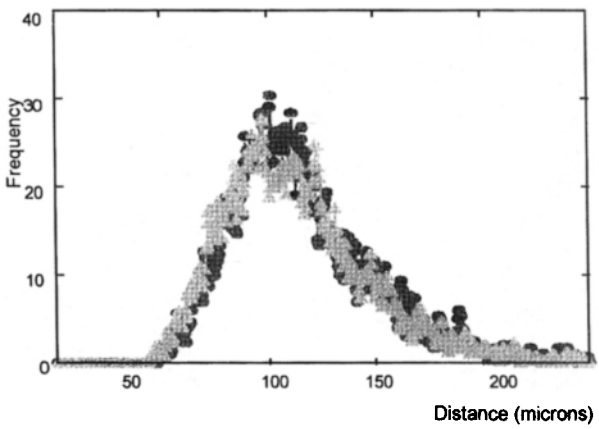

Fig 5. Average Spacing to 8 Nearest Fibres in a PGA Felt Scaffold by Image Analysis

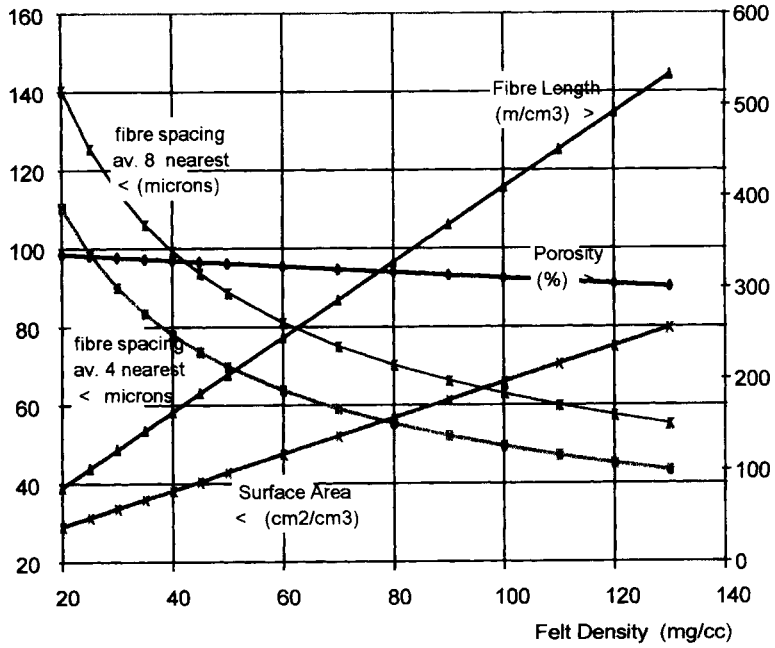

Fig 6. Calculated effects of variations in bulk density of felt scaffolds (2.44dtex PGA)

Shaped Scaffolds for the Meniscus

The meniscus has a complex shape and hence an appropriately shaped implant is necessary for its repair. This first requires a scaffold which has the correctly matched dimensions to guide the formation of the cultured tissue. The photographs in fig. 7 show the crescent shape and the curved triangular section of native meniscal tissue and a shaped scaffold constructed from bioresorbable poly-lactic acid fibres.

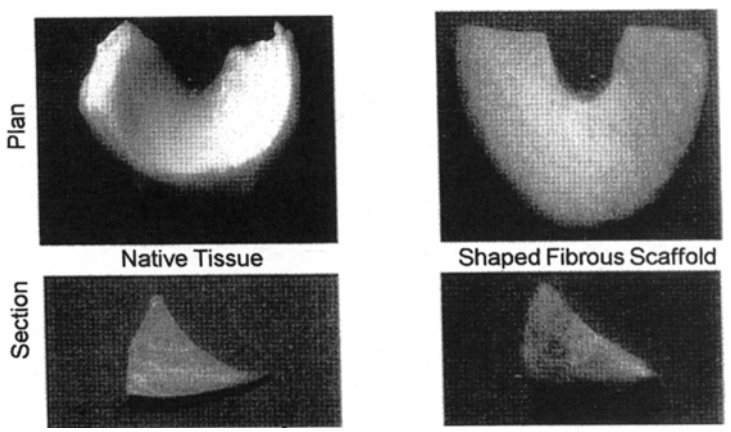

Fig 7. Example of native medial meniscus and shaped PLLA fibrous scaffold

REFERENCES

1. J Bulkwalter, L Rosenburg, E. Hunziker. 'Articular cartilage composition, structure, response to injury and methods of facilitating repair'.(Ed. J. Ewing) Articular Cartilage and Knee Function Basic Science and Arthroscopy, New York, Raven Press, 1990, 19 - 55
2. L.E. Freed, G Vunjak et al. 'Biodegradable Polymer Scaffolds for tissue engineering', Biotechnology 1994, 20, 689 - 693
3. M. Sittinger et al. 'Resorbable Polyesters in Cartilage Engineering: Affinity and Compatibility of polymer fibre structure to chondrocytes'. J. Biomed. Mater. Res. (Applied Biomaterials) 1996, 33, 57 -63.
4. C A Vacanti, R Langer, B Schloo, JP Vacanti. 'Synthetic polymers seeded with chondrocytes provide a template for cartilage formation'. Plast. Reconstr. Surg. 1991, 88, 753 - 759
5. E Frazza, E. Schmitt, 'A new adsorbable suture'. J. Biomed Mater. Res. 1971, 1, 43 - 58.
6. D K Gilding A. Reed, 'Biodegradable polymers for use in surgery, poly(glycolic) and poly (lactic acid) homo & copolymer'. Polymer, 1979, 20, 1459 - 1464
7. J Pachence, J Kohn. 'Biodegradable polymers for tissue engineering'. (Ed. Lanza, Langer, Chick) Principles of Tissue Engineereing, New York, Academic Press, 1997, 273 - 293.
8. S Huang, P Edelman. 'An overview of bio-degradable polymers and biodegradation of polymers'. (Ed. Scott, Gilead) Degradable polymers principles and applications, London, Chapman & Hall, 1995
9. G Naughton, J Mansbridge, G Gentzkow. 'A metabolically active human dermal replacement for the treatment of diabetic foot ulcers'. Artificial Organs, 1997, 21(11), 1203 - 1210.
10. R. Pecoraro, M Burgess, 'Pathways to diabetic limb amputation: Basis for prevention, Diabetes care' 1990, 13, 513 - 521.
11. J Cox, C Nye, W Scaefer, J Woodstein, 'The degenerative effects of partial and total resection of the medial meniscus'. Clin. Orthop. 1975, 109, 178 - 183.
12. K Athanasiou, et al 'Sterilisation, toxicity, biocompatibility and clinical applications of poly lactic acid / poly glycolic acid copolymers', Biomaterials 1996, 17(2), 93-102.
13. C Chu, L Zang, L Coyne, 'Effect of gamma irradiation and irradiation temperature on hydrolytic degradation of synthetic adsorbable sutures', J. App. Poly. Sci., 1995, 56, 1275-1294
14. E Wintermantel, et al 'Tissue engineering using superstructures', Biomater. 1996, 17(2), 83-91.

21. Functional Requirements of Bedding Materials for Elderly Patients

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1. INTRODUCTION

Incontinence means inability and controls the evacuation of urine or feces. Ebersole and Hess [1] mentioned that among the approximate 28 millions elders in the US community, 15% to 30% have urinary incontinence. Incontinence is present in 53% or more of nursing home residents. This translates into 1.5 million elder. The annual cost for incontinence is $7 million in the community and $3.3 million in nursing homes and $15 billion for care of incontinence of all people, young and old [2]. Often, fecal incontinence is associated with urinary incontinence. These symptoms, urinary or/and feces are commonly found in elderly patients who feel guilty, shamed and embarrassed to talk and they worry about the cost. Also, it is difficult for the medical staff and patients' relatives to cope with the incontinence elderly patients.

Norton [3] stated that nurses might fell embarrassed, both for themselves and for the patient. There may be guilt, since incontinence is sometimes interpreted as a sign of 'bad' nursing care. Anger with a patient is particularly difficult to admit. Anger may result from extra, unpleasant work created by incontinence, or because the patient is felt to be lazy, or wetting or purpose to gain attention or annoy the staff. Many of these feelings – revulsion, guilt, embarrassment, and anger – are understandable

Even slight incontinence can cause cold and wet sensation, unpleasant odor and sore skin, which can cause discomfort if hygiene is poor. Both urine and feces can cause direct skin irritation. They also provide a damp and warm environment, which is ideal for the proliferation of potentially pathogenic microorganism [4]. Also, this can lead to sickness such as colds. If the urine is left on the skin, it has to be washed before renewing the new bedding materials is necessary, but frequent washes of the incontinent elderly patient with the use of soap and water can loose the protective oil on the skin. In 1986, the Australian Kylie [5] draw sheet was introduced to address the problems. The Kylie draw sheet is composed of two layers. The top layer is porous and water repellent and the other layer is composed of absorbent material. However, the effectiveness of the draw sheet in the clinic environment was not reported.

The bedding for the elderly patients used in the Hong Kong hospitals is typically constructed in the following way. The bed mattress is first covered with a plastic sheet and then a cotton bed sheet of the same width is placed on the top and tucked in. On top of the cotton bed sheet, a plastic sheet is placed in the center of the bed and a white cotton draw sheet is then placed on the top. The sides of the draw sheets are tucked in. The existing draw sheets, used in the hospitals cannot keep the patients dry when being wetted or soiled. This may cause skin infections if draw sheet is not changed quickly and the affected parts of body are not wiped, which may further induce psychological problems as discussed by Palmer [6].

Urinary incontinence make elderly patients feel anxiety, depression, helplessness, sadness, pessimism, low self-esteem, stress, insecurity, anger, feeling undignified,

ashamed, self-blame, impatient, feeling of being an outcast, uncomfortable due to dampness, embarrassment, socially disruptive, loss of control, worry, social isolation, mourning and futility. The relatives of the patients have the feeling of burdensome, tiring, difficulty, anger and resentment. Meanwhile, health care providers have the feeling of avoidance, incontinence care seen as time consuming, frustrating, aesthetically displeasing, less sympathetic and more blaming [6].

Therefore, there is a strong need for designing the new functional bedding materials to improve the quality of life for patients and their relatives, and reduce the workload of the health care providers. Before new bedding materials are developed, we need sound understanding of the functional and emotional requirements of the elderly patients, their relatives and health care providers. However, there is no research work that has been reported on what are the requirements and attitudes from the end-of-users. Besides, the population in Hong Kong is aging and the population of the elderly (aged over 65) residents is growing like other developed countries, there is a strong social need in Hong Kong to address the urinary incontinent problems. Hence, the objective of this research paper is fill this knowledge gap by identifying the concerns and perceptual requirements on the draw sheets of elderly patients', their relatives' and health care providers.

2. METHODOLOGY

To obtain understanding of the problems and issues involved, observations were carried out on the behavior of elderly patients, the visiting and working patterns of patient' relatives and medical staff in the Division of Geriatrics in Queen Mary Hospital, Hong Kong. From the hospital visits and observations, we obtained the knowledge of the constructions of the existing bedding and working procedures in the hospital and the associated environment.

Personal interviews were held with the medical staff and patients' relatives to obtain more information about the daily routine work in the ward and the general emotional features of the elderly patients and their relatives.

Based on the results of literature review, hospital visits and personal interviews, three questionnaires were designed to identify the attribute profiles of existing bedding for elder patients perceived by the elderly patients, their relatives and medical staff. Also, the attribute profiles of ideal bedding are recorded from the respondents by another set of questions. Them, a pilot test was carried out on the 5 medical staff, 2 patients and 2 patients' relatives to test the questionnaires. After the pilot test, questionnaires were modified and formal surveys were conducted in nursing homes with 86 respondents, including 19 elderly patients who are below age of 65, 32 patients' relatives and 35 medical staff members.

SPSS is used for the statistical analysis. Preliminary analysis is carried out to identify the distribution of the data. Confidence intervals for means, medians and proportions are calculated to compare results of different groups.

3. RESULTS AND DISCUSSION

3.1 Pilot test

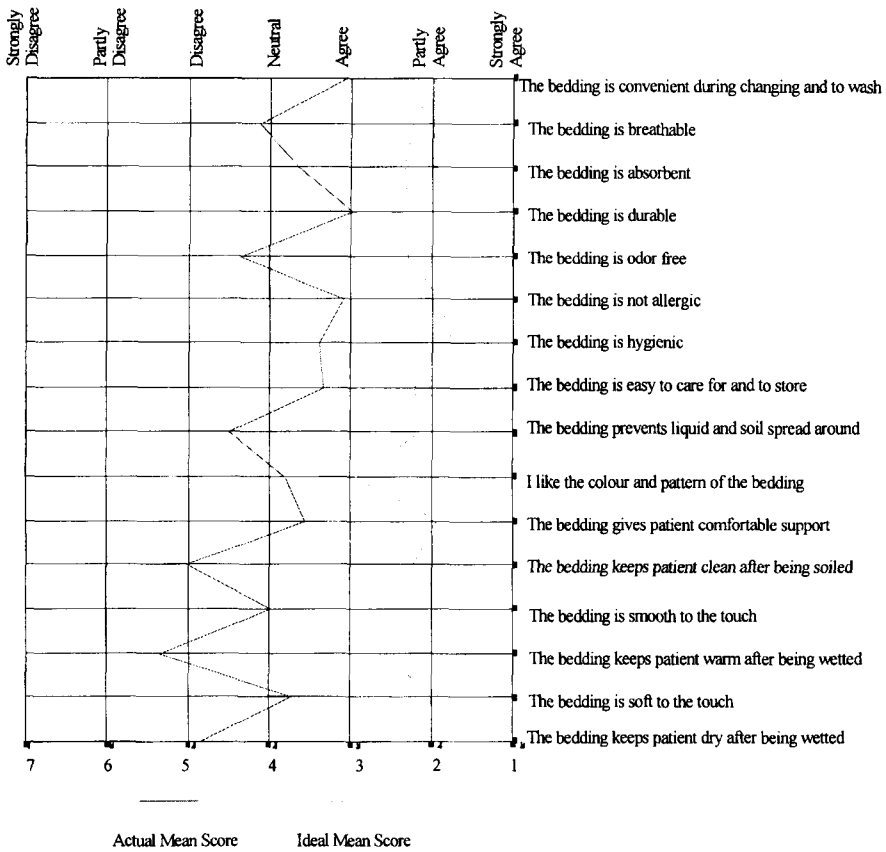
The results of the pilot test show that all the respondents are not satisfied with the functional performance of the existing bedding material used in the hospital. The

differences in the attribute profiles between ideal and existing bedding materials are significant for all the attributes surveyed.

3.2 Differences between existing and ideal bedding materials

Figure 1 shows that the differences in the attribute profiles are significant between the existing and ideal bedding. The requirements on the functional performance of the bedding material expressed as the ideal bedding are considerably higher those of the existing bedding, suggesting that the medical staff, elderly patients and their relatives are not satisfy with the performance of the existing bedding.

Figure 1 Attribute profiles of existing and ideal bedding from all the respondents



Six attributes were indicated in the range of "neutral to disagree" on the functional performance, including:

- The bedding keeps patient warm after being wetted;
- The bedding keeps patient clean after being soiled;
- The bedding keeps patient dry after being wetted;
- The bedding prevents liquid and soil spread around;
- The bedding is odor free;

➢ The bedding breathable.

"Patient's dryness after being wetted" is the attribute that has the largest score difference (2.83) between the existing and ideal bedding, followed by "patient's warmness after being wetted" (2.80) and "patient's cleanness after being soiled" (2.80). In other word, the respondents perceived that the bedding could not keep the patient dry and warm after being wetted and clean after being soiled. The rating of existing bedding on "durability of the bedding" is the closest to that of ideal bedding (0.70 in difference), suggesting that the durability of the bedding be close to their expectation.

3.3 Differences among the three groups of respondents

Figure 2 compares the ratings of the three groups of respondents on the attribute "dryness of the bedding and patient after being wetted" towards the existing bedding and ideal bedding. The existing bedding was rated consistently more unsatisfactory than the ideal bedding among the medical staff, elderly patients and their relatives. Also, the ratings from elderly patients are more variable, comparing with the other two groups.

Figure 2 The bedding keeps patient dry after being wetted

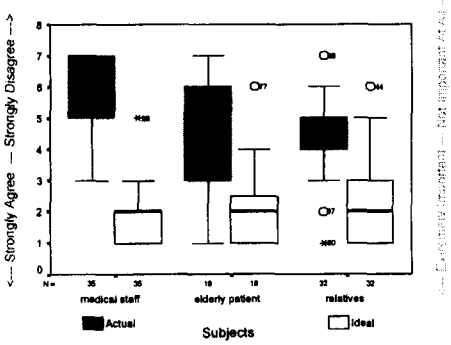


Figure 3 The bedding keeps patient warm after being wetted

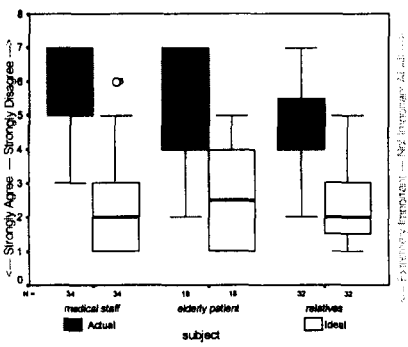


Figure 4 The bedding keeps patient clean after being soiled

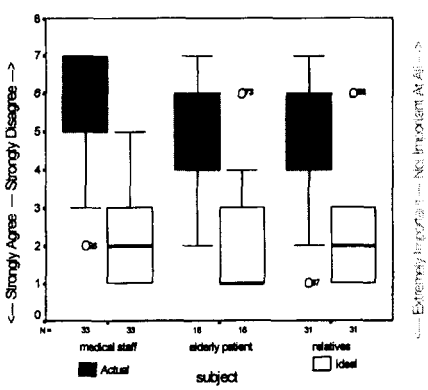
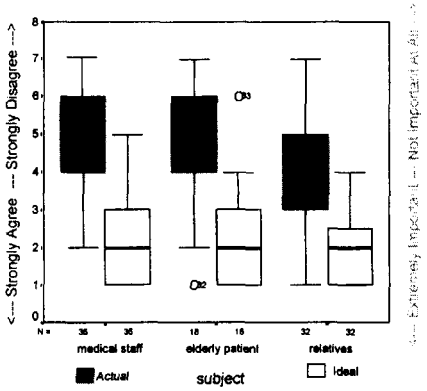


Figure 5 The bedding prevents liquid and soil spread around



Similar patterns are found in the ratings on the attribute "The bedding keeps patient warm after being wetted", as shown in Figure 3. This indicates that most of the respondents perceive that the existing bedding does not provide enough (far from ideal) warmness to the patient after being wetted.

In Figure 4, ratings on attribute "The bedding keeps patient clean after being soiled" are compared among the three groups of respondents. Obviously, all the three groups of respondents do not satisfy the performance of the existing bedding, as the rating existing bedding are significantly different from the ideal one. In an associated attribute on "The bedding prevents liquid and soil spread around", similar pattern was observed in Figure 5, indicating that the existing bedding cannot prevent the soil and liquid spread around as it is perceived by the three groups of respondents.

Figure 6 The bedding gives patient comfortable support

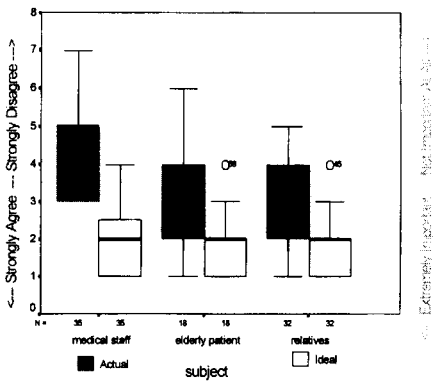
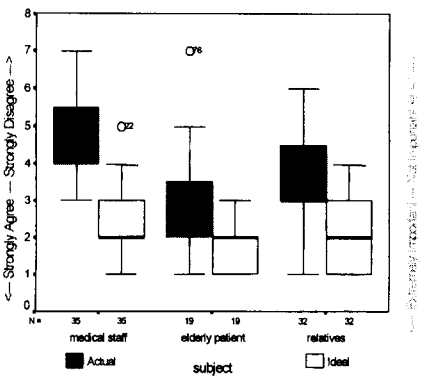


Figure 7 The bedding is soft to the touch



In the attributes associated with the mechanical features of the bedding, smaller differences were found in the three groups of respondents, as shown in Figure 6 and Figure 7. However, the respondents are still rate the existing bedding on attributes of "comfortable support" and "soft to the touch" lower than the ideal bedding.

Figure 8 The bedding is hygienic

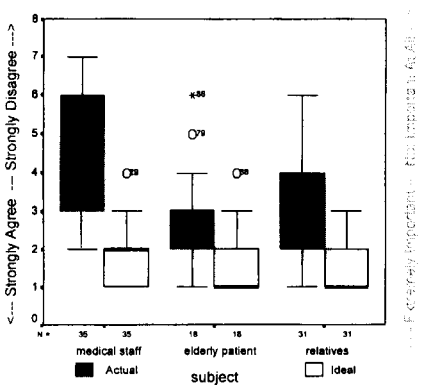
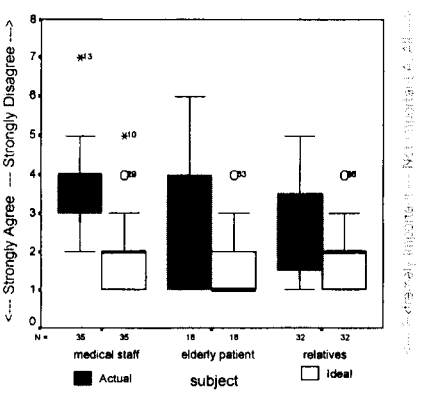


Figure 9 The bedding is convenient during changing and to wash



In terms of hygiene and easy-care, the differences between existing bedding and ideal bedding is considerably smaller, comparing with other attributes, as shown in Figure 8 and 9. It is worth to note that medical staff rated the existing bedding more significantly lower than the ideal bedding in terms hygiene and easy care, while the patients and their relatives rated the existing bedding more close to the ideal one. The differences among the different groups may be due to the differences in their daily dealing with the bedding and their different roles in the urinary incontinence.

Table 1 Significance of differences in individual group's ratings between the existing bedding and ideal bedding

Question	Staff	Elderly	Relative	Overall
1. The bedding keeps patient dry after being wetted				
2. The bedding is soft to the touch				
3. The bedding keeps patient warm after being wetted				
4. The bedding is smooth to the touch		x		
5. The bedding keeps patient clean after being soiled				
6. The bedding gives patient comfortable support				
7. I like the colour and pattern of the bedding		x	x	
8. The bedding prevents liquid and soil spread around				
9. The bedding is easy to care for and to store				
10. The bedding is hygienic				
11. The bedding is not allergic				
12. The bedding is odor free				
13. The bedding is durable		x		
14. The bedding is absorbent		x		
15. The bedding is breathable		x		
16. The bedding is convenient during changing and to wash				

Note: x = Not significant

We used paired t-test to examine the significance of the differences in the attributes between the existing and ideal bedding quality amongst the medical staff, elderly patients and their relatives. As shown Table 1, the medical staff rated the existing bedding significantly unsatisfactory on all the attributes in comparison with their expectation. This may be due to their profession or expertise in this area, so they expect better performance of the bedding. The relatives of the elderly patients have similar responses except on the attribute of *color and pattern* of the bedding with no significant difference. The elderly patients themselves are unsatisfied with 11 attributes of the existing bedding and satisfied on five of the attributes, including the *smoothness, durability, absorbency, breath and color and pattern* of the bedding.

CONCLUSION

Through hospital observations, personal interviews and surveys, sixteen attributes are identified for bedding used for elderly incontinent patients. Comparing the responses to existing bedding and ideal bedding, we found that the three groups of respondents (elderly patients, their relatives and medical staff) are not satisfied with existing bedding. Especially, the attributes associated dryness and warmth of the bedding are considered to be strongly unsatisfied for urinary incontinent patients. For the 16

functional attributes surveyed, the perceived functional performance of existing bedding materials was significantly below that of expected or ideal bedding materials. These results suggest that there is a strong need to design and develop innovative bedding to improve the functional performance of the bedding used for elderly urinary incontinent patients, especially in the area of thermal and moisture functional performance.

Acknowledgment

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REFERENCE

1 Ebersole Priscilla, Hess Patricia, "Toward healthy aging: human needs and nursing response', Mosby-Year Book, Inc., 1997, 5th ed., p. 288, 297- 298.

2. U.S. Department of Health and Human Services, Clinical Practice Guidelines, 1992

3. Norton, Christine, 'Nursing for continence', Beaconsfield, Bucks: Beaconsielf Publisher, 1996, 2nd ed., p. 1-11.

4. Norton, Christine, 'Nursing for continence', Beaconsfield, Bucks: Beaconsielf Publisher, 1996, 2nd ed., p. 76-101.

5. Norton, Christine, 'Nursing for continence', Beaconsfield, Bucks: Beaconsielf Publisher, 1996, 2nd ed., p. 166.

6. Palmer, Mary H., 'Urinary continence: assessment and promotion', Gaithersburg, Md: Aspen Publishers, 1996, p. 115.

Session 5: Implantable devices

22. Time Dependent Behaviour of Some Suture Materials

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INTRODUCTION

In a clean incised wound, the fundamental purpose of suture placement is to oppose the wound edges until the tissue is strong enough to withstand the normal tensile forces without mechanical support that is, until the healing process has progressed sufficiently (2, 14, 11).

Important characteristics of suture materials are adequate tensile strength during the critical wound healing period, excellent knot security, improved surface properties, elasticity enough to be in harmony with mechanical forces, adequate static and dynamic fatigue life, minimal reaction in the tissue and easily sterilization. Therefore, in recent years, so many different types of sutures with different performance characteristics have been developed (4, 6, 7).

The importance of suture material in the maintenance of wound integrity has been recognised for centuries. When a suture fails to perform its functions, the consequences may be disastrous. For example, massive bleeding may occur when the suture loop surrounding a vessel is disrupted and when a suture in an abdominal wound unties or breaks, evisceration may follow (9, 12).

The suture material in the living tissue is subjected to various factors like knot tension, tensile tension, loop tension, creep, relaxation, static and dynamic fatigue, knot slippage and tissue reaction. Therefore, it is very difficult to asses the behaviour of suture in the body. In order to choose the suitable suture for tissue before the operation, surgeon needs to know the effect of mechanical deformations on the suture performance.

A suture is in the form of a loop around the wounded tissue and keep the wound edges approximate by a knot until the healing has been obtained. We know that injured tissues have eudema for the limited period. When the constant loading due to eudema is applied to the suture material, it will increase in length immediately and then continue extending until it reaches a state of equilibrium. This behaviour of suture placed in the tissue, especially in the wounds which have eudema, may highly affect the healing process. Furthermore, when a suture material is stretched and then held at the new length, tension gradually falls. For the clinical application, it is important to know how long and how strongly the tension of sutures would be maintained. Because of the behaviour of sutures, tight approximation of the injured tissue couldn't be continued and this may cause important consequences in the surgical procedures. Therefore, sutures are subjected to time-dependent forces rather than tensile forces (8, 13).

Time-dependent behaviour, such as creep and recovery and stress relaxation, of sutures has vital importance on the performance during healing period to keep the approximation of the wound edges rather than tensile and knot strength properties. Therefore in this study, time-dependent behaviour of sutures, that is paid less attention so far, has been investigated.

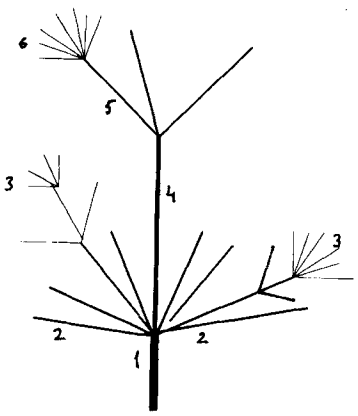
EXPERIMENTAL

Material

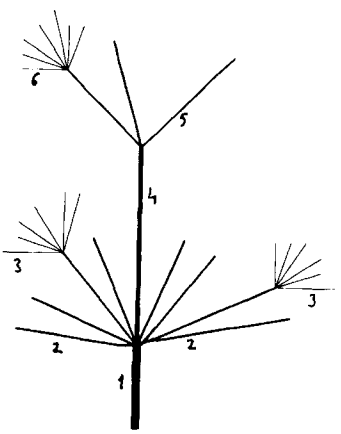
In this study, four different types of non-absorbable suture materials namely Silk, Polyester, Polyamide and Polypropylene kindly supported by Dogsan Surgical Materials Ltd. were tested. They are all 2/0 in diameter. In order to see the effect of structure on the time-dependent behaviour, two monofilament and two braid structures have been used. Table 1 gives the properties of the materials. Fig. 1 and 2 show the braid analysis of the Silk and Polyester suture materials, respectively. Table 2 gives the detail of these analysis.

Suture	Origin	Structure	Surface Procedure	Size (USP)	Number (Tex)	Thickness (mm)
Silk	Natural	Braid	Silicon	2/0	99	0.38
PET	Synthetic	Braid	Silicon	2/0	99	0.36
PA	Synthetic	Monofilament	None	2/0	107	0.34
PP	Synthetic	Monofilament	None	2/0	80	0.34

1.Properties of the Test Suture Materials (1)



1. Braid Analysis of the Silk Suture (1)



2. Braid Analysis of the Polyester Suture (1)

Parameters	Silk	Polyester
Pick count		65
Denier of braid yarn (1)	891	891
Number of sheath yarn (2)	8	8
Denier of sheath yarn (2)	75	78
Number of filaments (3) in every sheath yarn	66	18
Denier of core (4)	306	288
Number of yarns (5) in the core	3	3
Denier of yarns (5) in the core	102	96
Number of filaments (6) of every yarn in the core	97	32

2. Braid Parameters of Silk and Polyester Suture Materials (1)

Pick count: The number of strands rotating in one direction in one cycle length divided by the cycle length

Method

Prior to tests, all suture materials were conditioned under the standart atmospheric conditions (%65 humidity and 21 C) for 24 hours.

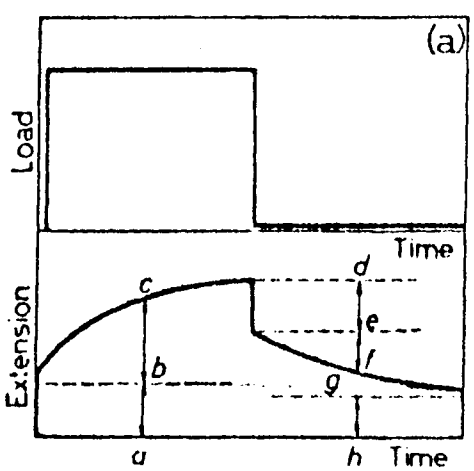
Creep and Recovery Tests

Sutures implanted in the body should keep their dimensional stability even if subjected to small tensions in long terms. This is an important parameter to choose suitable suture. Creep tests applied to sutures enable us to measure deformation mechanism under constant tension. Creep is the measure of increase in length during a period of time under constant tension. Creep behaviour of the sutures depends on the application time and the magnitude of the applied load. If the load is removed after certain time, suture tends to return its original length. This behaviour known as recovery. After removal of the load, all sutures show permanent elongation depending on the type and the structure (8, 10, 3, 5).

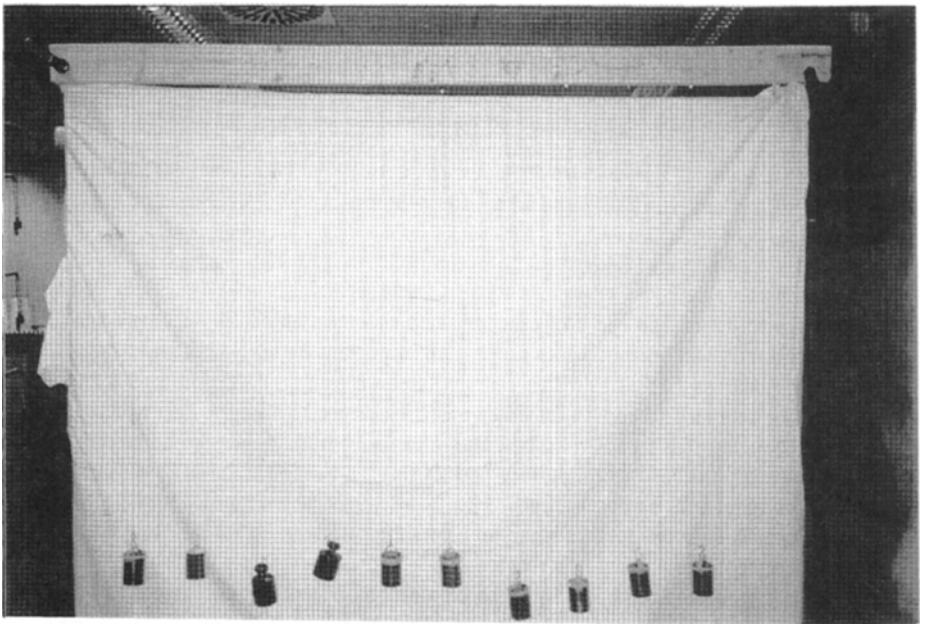
On the application of a load to a fibre, it will, after an instantaneous extension, continue to extend as time goes on; and, on removal of the load, the recovery will not be limited to the instantaneous recovery but will continue to take place. This behaviour is illustrated in Fig. 3 and is known as creep and creep recovery.

The instantaneous extension is followed by creep. The removal of load gives rise to an instantaneous recovery, usually equal to the instantaneous extension, followed by a further partial recovery with time, which still leaves some unrecovered extension. The total extension may therefore be divided into three parts; the immediate elastic deformation, which is instantaneous and recoverable; the primary creep, which is recoverable in time; and the secondary creep, which is non-recoverable.

In this study, 10 Newton of load is applied to the sutures to study creep and recovery behaviour. The tests were carried out on the instrument shown in Fig.4. Measurements of change in length of the suture were recorded every 10 minutes for one hour and then every half an hour until no change in length observed, for both creep and recovery, later the data collected were prepared as a time against length graphic.



3.Creep and Recovery Graphic (10)

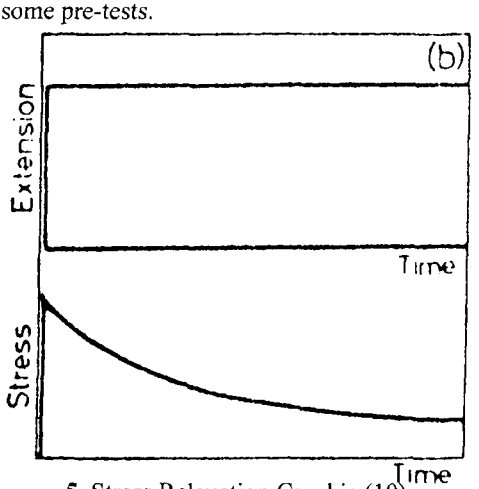


4. The Instrument, where creep and recovery tests were carried out (1)

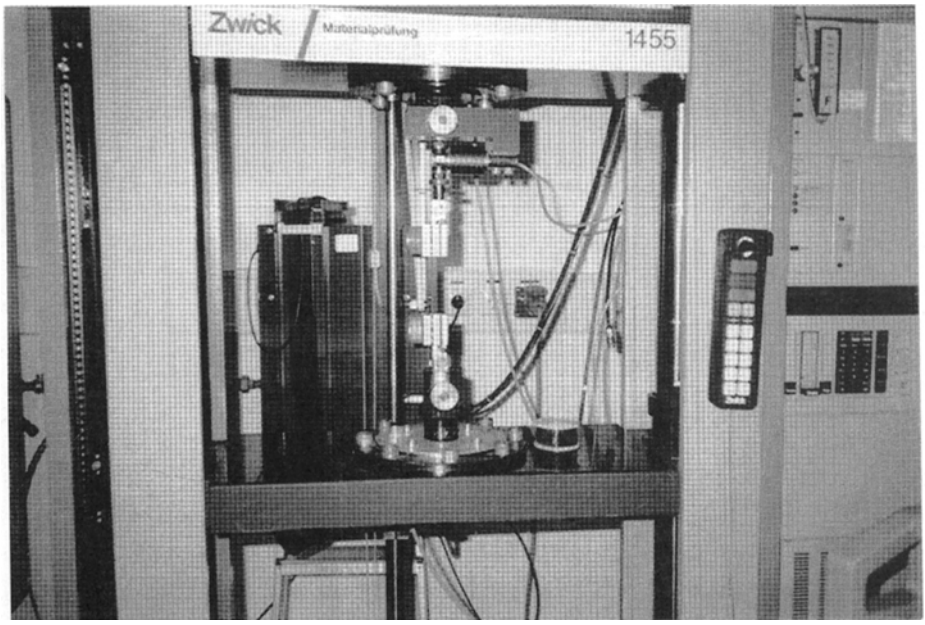
Stress Relaxation

Creep is extension with time under an applied load: the complementary effect is relaxation-the reduction of stress with time under a given extension, see Fig. 5. When the fibre is stretched, an instantaneous stress is set up, but this gradually decreases as time passes. It may drop to a limiting value or may disappear completely. This phenomenon is known as relaxation (10). From Fig. 5 it appears that, after a rapid initial decay of stress, the rate of decay drops to zero.

Zwick 1455 Tensile Tester was used to perform the tests, see Fig. 6. Suture was placed between the jaws and the gauge length was set to 8 cm. A load of 30% of the maximum breaking strength was applied to specimen. When this load is reached, the new length of the specimen was kept constant. A graphic of time against decrase in applied tension was recorded by the computer. 30 minutes of test time was decided to be enough after making some pre-tests.



5. Stress Relaxation Graphic (10)

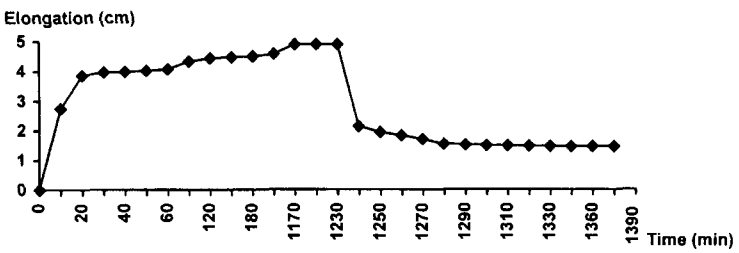


6. The Instrument where stress relaxation carried out (1)

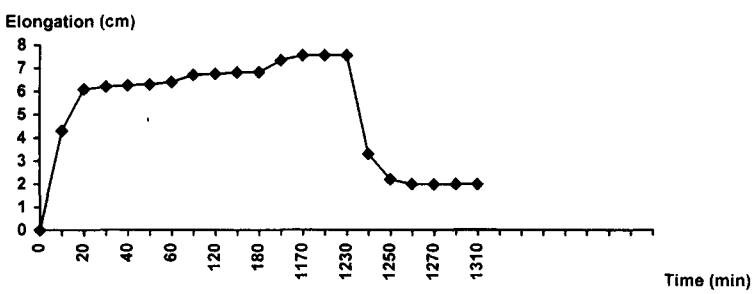
RESULT AND DISCUSSION

Creep and Creep Recovery

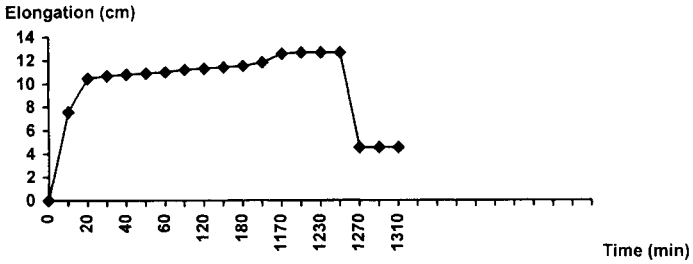
Fig. 7-10 give the results obtained from the creep tests.



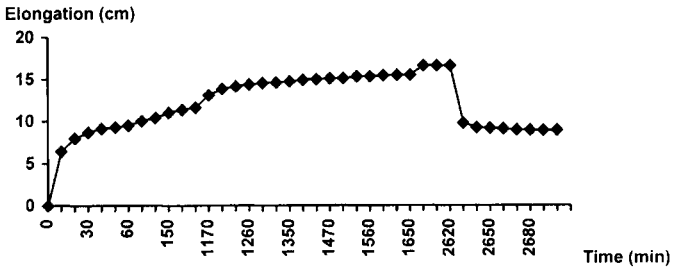
7. Creep and Recovery Graphic of Silk Suture (1)



8. Creep and Recovery Graphic of Polyester Suture (1)



9. Creep and Recovery Graphic of Polyamide Suture (1)



10. Creep and Recovery Graphic of Polypropylene Suture (1)

Suture	Total Creep Time (min.)	Total Recovery Time (min.)	Total Elongation (cm)	Total Recovery Length (cm)	Elongation in First 10 min. (cm)	Recovery in First 10 min. (cm)	Permanent Elongation (cm)	Total Recovery (%)
Silk	1230	150	4.89	3.43	2.75	2.75	1.46	70
PET	1230	80	7.53	5.54	4.30	4.30	1.99	74
PA	1260	50	12.60	8.14	7.56	8.14	5.54	64
PP	2620	150	16.60	7.70	6.42	6.82	8.90	46

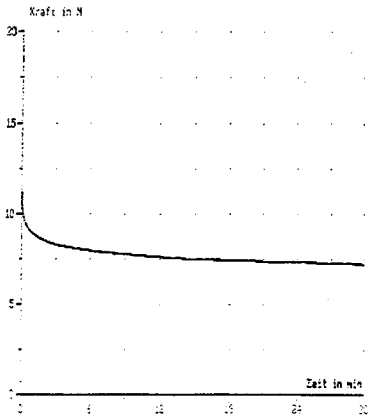
3. The Results obtained Creep and Creep Recover Tests (1)

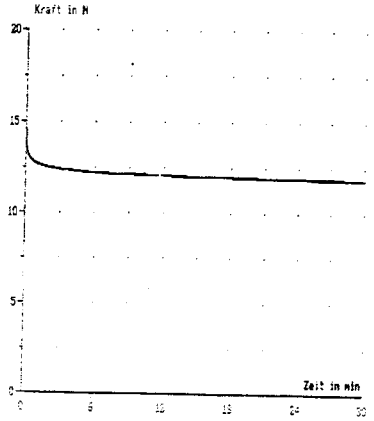
Analysis of the creep and creep recovery results here made from the graphics. The graphics were divided into four main regions. Initial elongation and initial recovery (first 10 minutes), primary creep (between 10 min.-20 min.), secondary creep (after 20 minutes) and permanent elongation. Table 3 gives the results obtained from the graphics as mentioned above.

Polypropylene shows the longest creep time and the highest initial elongation. It has also highest permanent elongation and lowest recovery rate. Silk and Polyester show similar behaviour in terms of initial elongation, total creep and total recovery time, and recovery rate. Polyamide shows similar behaviour with Polypropylene.

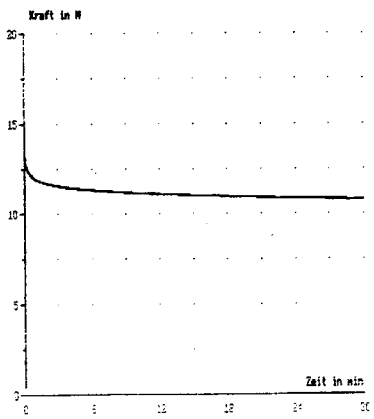
Stress Relaxation

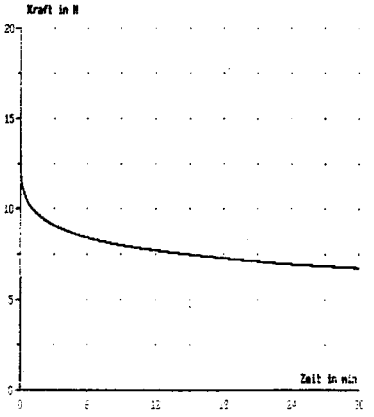
Fig. 11-14 show stress-relaxation graphics of the sutures. All sample were stretched until 30% of the maximum breaking load had been reached. They then kept constant at this new length for about 30 minutes. The fastest stress relaxation rate was observed within first 10 minutes. 30 minutes of total relaxation time was decided to be enough to analyse the relaxation behaviour due to pre-tests results.





11. Stress Relaxation Graphic of Silk Suture **12.**Stress Relaxation Graphic of PET Suture





13. Stress Relaxation Graphic of PA Suture **14.** Stress Relaxation Graphic of PP Suture

Table 4 gives the results obtained from relaxation graphics.

All four sutures show different relaxation behaviour. Silk, Polyester and Polyamide sutures show similar relaxation rate initially. Polyamide has the highest loss in strength. After 30 minutes of testing time Polyester has the lowest loss in strength. In another words, it keeps most of its strength. Polypropylene, however, loses its most of strength. Silk also loses its 40% of strength.

Suture	**Load**	**Initial Elongation**	**Stress Relaxation (%)**							
	(N)	(%)	Initial	30 sec.	1 min.	3 min.	6 min.	10 min.	15 min.	30 min.
Silk	11.7	2.8	7.9	20.9	23.8	28.8	31.6	33.8	35.9	38.1
PET	14.8	4.5	6.8	12.2	13.9	16.1	16.7	17.8	18.4	19.8
PA	14.5	9.1	10.3	17.2	18.0	19.5	21.9	22.4	23.6	25.5
PP	12.9	5.7	8.3	17.6	21.2	29.6	34.1	39.3	41.9	48.1

4. The Results Obtained Stress Relaxation Tests (1)

CONCLUSION

Time-dependent behaviour of sutures plays very important role on assessing their performance during-and post-operation. Creep and creep recovery and stress relaxation are important time-dependent behaviours of the materials. For sutures, however, they play vital role and the information about them gives very valuable data to surgeon. Especially, during post-operation period, sutures undergo time-dependent deformations such as swelling of the wound, stress applied to keep the divided wound edges.

In this study, effect of suture structure (braid or monofilament) on the time-dependence behaviour was investigated. It can be concluded that creep and recovery behaviour depends on the suture structure rather than suture's origin such as Polyester or Polyamide or synthetic or natural. This, however, can not be said for the relaxation behaviour. It seems like suture's origin play rather important role. It seems like when the material held at constant length molecular structure is effective on stress relaxation.

REFERENCES

1 E K Bayraktar, *Investigation of Effects of Monofilament and Braid Structures Of Silk, Polyamide 6, Polyester, Polypropylene Sutures on Some of the Mechanical Properties,* Ph.D. Thesis (unpublished), University of Uludag, 1999.

2 R B Bourne, F H Bitar, P R Andreae, L M Martin, J B Finlay, F Marquis, "In-Vivo Comparison of Four Absorbable Sutures:Vicryl, Dexon Plus, Maxon and PDS", *The Canadian Journal of Surgery*, 1988 31(1) 43-45.

3 J E Brouwers, H Oosting, D De Haas, P J Klopper, "Dynamic Loading of Surgical Knots", *Surgery Gynecology&Obstetrics*, 1991 173(12) 443-448.

4 A Browning, *Annealing and Its Effect on the Hydrolytic Degradation of Poly(glycolic acid) Absorbable Sutures in Vitro,* M.Sc.Thesis (unpublished), Cornell University, 1984

5 C C Chu, Z .Kizil, "Quantitative Evaluation of Stiffness of Commercial Suture Materials", *Surgery Gynecology&Obstetrics*, 1989 168(3) 233-238.

6 C C Chu, *Recent Advancements in suture Fibers for Wound Closure. High-Tech Fibrous Materials*, USA, American Chemical Society, 1991.

7 J B Herrmann, "Tensile Strength and Knot Security of Surgical Suture Materials", *Annals Surgery*, 1971 37(4) 209-217.

8 Dan E W Holmlund, "Physical Properties of Surgical Suture Materials", *Annals Surgery*, 1976 184(2) 189-193.

9 S A Metz, J A Von Fraunhofer, B J Masterson, "Stress Relaxation of Organic Materials", *Biomaterials,* 1990 11(4)197-199.

10 W E Morton, J W S Hearle, "Physical Properties of Textile Fibres", New York, John Wiley and Sons Inc., 1975.

11 K M G Paez, A C San Martin, J V G Sestafe, E Jorge-Herrero, I Milan, R Navidad, A Cordon, J L Castillo-Olivares, "Resistance and Elasticity of the Suture Threads Employed in Cardiac Bioprostheses", *Biomaterials*, 1994 15(12) 981-984.

12 J G Thacker, G Rodeheaver, J W Moore, J J Kauzlarich, L Kurtz, M T Edgerton, R F Edlich, "Mechanical Performance of Surgical Sutures", *The American Journal of Surgery*, 1975 130(9) 374-380.

13 N Tomita, S Tamai, T Morihara, K Ikeuchi, Y Ikada, "Handling Characteristics of Braided Suture Materials for Tight Tying",*Journal of Applied Biomaterials*, 1993 4 61-5

14 W Van Winkle, C Hastings, "Considerations the Choice of Suture Material for Various Tissues", *Surgery Gynecology&Obstetrics*, 1972 135(7) 113-126.

23. Surface Treatment of the Textile Graft Which Reduces Thrombogenicity and Improves Healing

R. Maini

Sulzer Vascutek Ltd

Polyester based textile vascular grafts have been successfully used for many years for the replacement of larger diameter arteries of 8mm in diameter and over. Polyester is known to be a relatively thrombogenic biomaterial and in order to extend the application of these textiles to smaller diameter arteries it would be useful to reduce the thrombogenicity of such vascular grafts. A surface treatment (Fluoropassiv) has been developed to achieve this objective and it will be described together with results on reduced thrombogenicity and enhanced healing.

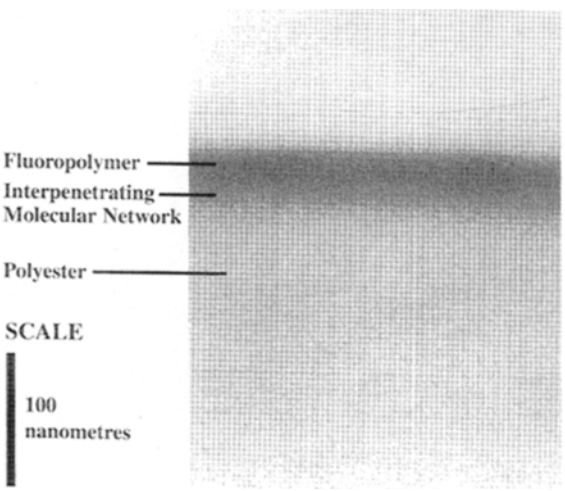
THE FLUOROPASSIV PROCESS

Fluoropassiv is a patented surface treatment of polyester textile (Ref. 1). The polyester textile is contacted with a solution of fluoropolymer (polyvinylidene fluoride) in an organic solvent. This organic liquid opens the surface structure of the polyester as it is a swelling agent for polyester. The fluoropolymer enters the surface layer of the polyester fibre. After the solvent is removed the polyester is covered with an extremely thin (~40 nanometre) glaze of fluoropolymer which is welded to the polyester.

Characterisation of Coating

The presence of the fluoropolymer surface has been confirmed by the use of Time of Flight Secondary Ion Mass Spectroscopy. The spectra clearly shows the presence of fluorine ions and the complete masking of the polyester signal.

Transmission Electron Microscopy at high resolution has been carried out by Dr Tetley at the University of Glasgow using ZLTEM (Zero loss TEM). This clearly shows (Fig. 1) the presence of a very thin fluoropolymer layer on top of the polyester with a mixed layer (interpenetrating network) in-between.



1. ZLTEM Magnification 275 000 x

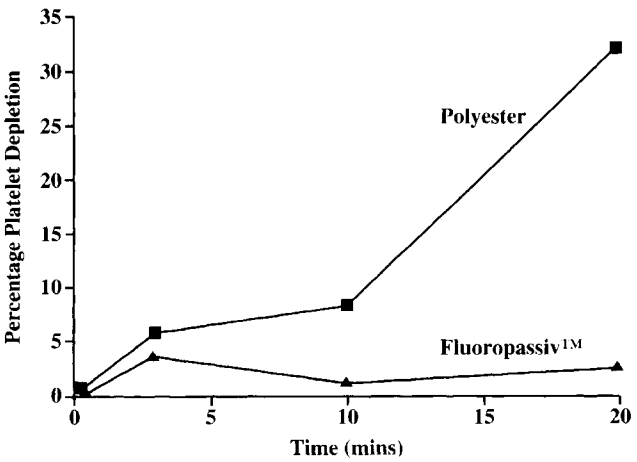
Thrombogenicity Tests

Thrombogenicity tests using human platelet rich plasma have shown reduced thrombogenicity of the composite Fluoropassiv treated material over base polyester (Fig. 2). Ex vivo chamber studies using radiolabelled platelets have also provided evidence of this markedly reduced thrombogenicity (Fig. 3).

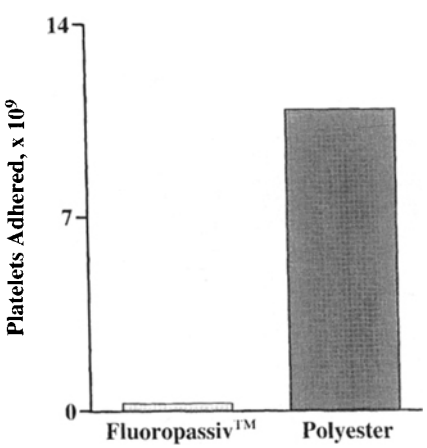
Healing

Explants of Fluoropassiv grafts and base polyester grafts have confirmed a much more rapid healing (tissue incorporation and endothelialisation) for the surface treated material.

Prof. Guidoin in a thoraco abdominal model has noted increased endothelialisation in comparison to controls and increased vasa vasorum formation (Ref. 2). These findings have also been confirmed by the work of Curti et al in a sheep carotid model (Ref. 3).



2. In Vitro Comparative Platelet Depletion



3. Ex Vivo Comparative Platelet Adherence

CONCLUSION

A new composite vascular biomaterial composed of a polyester core and ultrathin fluoropolymer covering reduces the thrombogenicity of polyester and improves its healing characteristics. Vascular prostheses made of this biomaterial are now being used for peripheral 6mm grafts and also for carotid patching, both applications in which lowered thrombogenicity is an important factor.

References

1. Paton et al, Fluorinating Polymer Surfaces, US Patent Office, Pat No 5,356,668 October 18, 1994.

2 R Guidoin et al, 'The Benefits of Fluoropassivation of Polyester Arterial Prostheses as Observed in a Canine Model', *ASAIO Journal*, 1994 **40** (3) 870-879.

3 T Curti et al, 'Biocompatibility of the new Fluoropassiv vascular prosthesis; Ultrastructural analysis', *Giornale Italiano di Chirurgia Vascolare*, 1994 **1** (1-2) 27-30.

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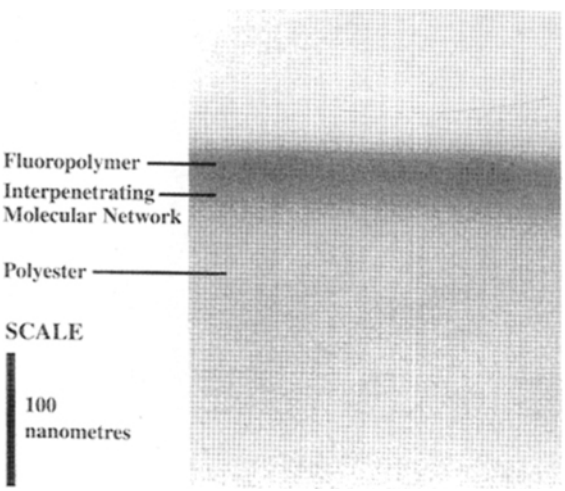

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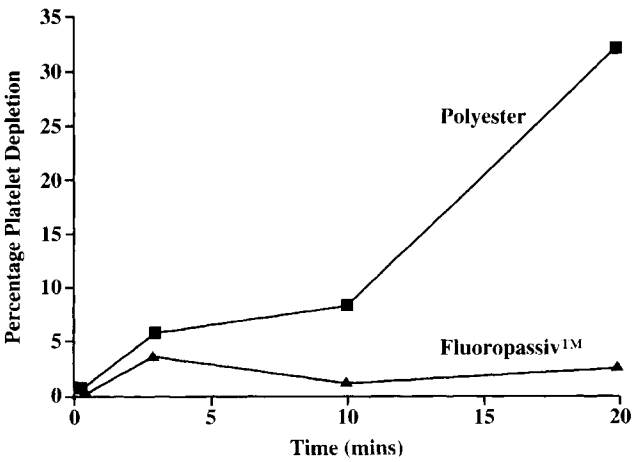

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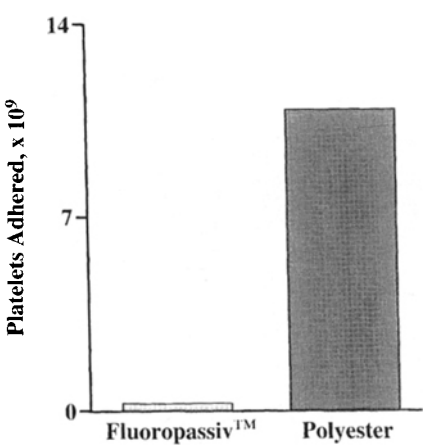

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1. Paton et al, Fluorinating Polymer Surfaces, US Patent Office, Pat No 5,356,668 October 18, 1994.

2 R Guidoin et al, 'The Benefits of Fluoropassivation of Polyester Arterial Prostheses as Observed in a Canine Model', *ASAIO Journal*, 1994 **40** (3) 870-879.

3 T Curti et al, 'Biocompatibility of the new Fluoropassiv vascular prosthesis; Ultrastructural analysis', *Giornale Italiano di Chirurgia Vascolare*, 1994 **1** (1-2) 27-30.

24. Embroidery Technology for Medical Textiles

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ABSTRACT

Textile structures are widely used as medical implants to replace and support soft and load bearing tissues and they serve as scaffolds in tissue engineering applications. In this study the potential of embroidery technology is investigated for the development of textile scaffold structures for tissue engineering and for medical applications. In a comparative experimental study the influence of ingrowing tissue on the mechanics of the thereby formed vital-avital composite has been investigated. An interlock knitted fabric has been compared to a specially designed embroidered fabric and a gelatine matrix has been used to simulate the ingrown tissue. It could be shown that due to the specific structure of the embroidery, stiffening effects known from other textiles i.e. woven and knitted fabrics could be inhibited. This observation together with the potential structural variety of embroidered fabrics, makes them interesting candidates for medical textiles applied to mechanically stressed tissues.

INTRODUCTION

In tissue engineering, textiles are used as scaffolds for their ability to provide optimal spatial and nutritional conditions for cell maintenance by the arrangement of structural elements, such as pores and fibers [1]. Tissue engineering textiles have been introduced for the development of different tissues in vitro such as liver, skin, bone, cartilage and muscle involving nonwoven, woven and knitted fabrics. In clinical applications, complications of implanted textiles are often associated with mechanical and structural incompatibility between implant and host tissue. An example are polymer meshes for abdominal wall repair. It was found, that specific surface area and porosity as well as elastic properties of the mesh determine the inflammatory reaction leading either to rapid vascularisation or to formation of a connective tissue capsule around the implant and subsequent loss of mobility of the abdominal wall [2, 3].

Embroidery technology allows to build up highly architectured 3-dimensional structures which are needed to integrate structure dependent functions e.g. pore patterns

or elements to control the mechanical behaviour. The flexibility of this technology allows to realize prototypes of a designed fabric within hours, without any hardware modification of machinery. Embroidery technology allows an almost unlimited integration of various thread like materials in a basic fabric. However, this technology, until today, had no known application in medical or technical textiles in general. The aim of this study is to scan the potentials that embroideries might offer as future medical textiles.

DESIGN OF TECHNICAL EMBROIDERIES

All embroidered textiles in this study were realized by Bischoff Textiles, Switzerland. The usual production process of embroideries consists of several steps: First a technical drawing of the textile design is generated which serves as a blueprint for the control data of the embroidery machine. Usually the designed pattern will be embroidered onto a polyvinylalcohol (PVA) or a cellulose acetate fabric, which is etched away afterwards either by washing in hot water or acetone respectively. Depending on the application, the supporting fabric may be a functional element of the textile e.g. a porous (nonwoven, woven or knitted) or dense membrane. To illustrate the possibilities of embroidery technology for biomedical applications, two examples of different textile architectures are presented.

Example 1: Textile scaffolds for cell culture studies

To investigate the interactions between cells and different yarn materials *in vitro* there is a need for suitable model systems [4]. A textile scaffold using embroidery technology was developed that consists of radially outspreading single yarns inside a circle. It was designed to fit into standard cell-culture plates with 6, 12 or 24 wells respectively (figure 1 A). The textile fabrication process, giving reproducible samples, will allow to investigate the motility, proliferation and differentiation of cells *in vitro* depending on different yarn properties such as material, surface treatment, texturation and yarn titer as well as local fiber concentration and fiber crossing angles. In the shown example (figure 1 B, C) polyester yarns (polyethylenterephtalate, PET) of different texturations were used. The scope of this example is to investigate the cellular organisation inside and between the yarns depending on yarn texturation and yarn material. This knowledge will help to optimize the design of textile scaffolds that are used as *in vitro* cultured cell transplantation devices .

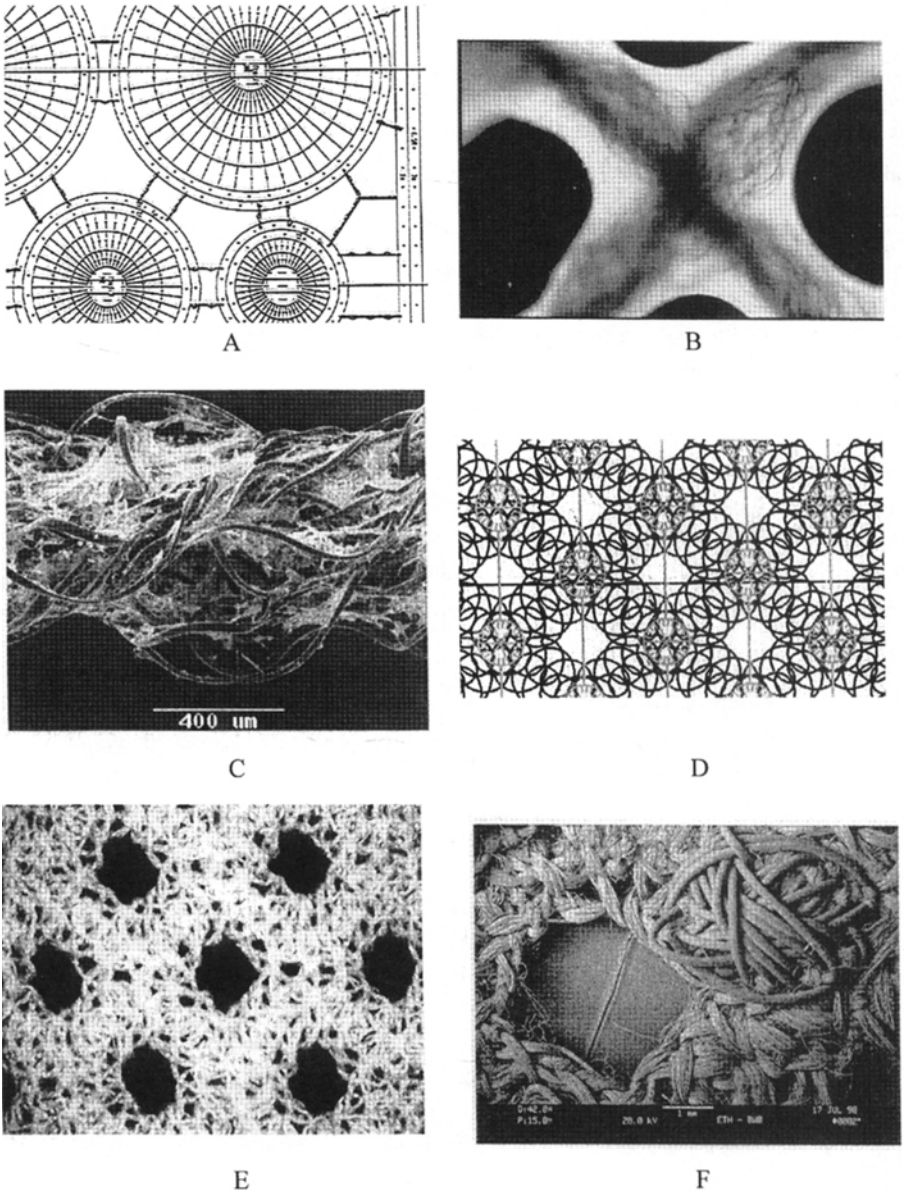

Figure 1. Examples of technical embroideries. (A) technical drawing of textile test scaffolds of example 1, (B) 3T3 fibroblasts on a textile scaffolds at 24 days in vitro, (C) SEM image of 3T3 fibroblasts grown 14 days in vitro on a textured PET yarn in an embroidered scaffold, (D) technical drawing of the textile wound dressing of example 2, (E) photograph showing the porous textile structure of the embroidered wound dressing, (F) SEM micrograph showing the textile structure of the wound dressing with integrated stiff monofilament elements for mechanical stimulation of the wound.

Example 2: Textile for an angiopolar [5] wound dressing system

Currently a new textile based wound dressing system to be applied to chronically non healing wounds is being developed. One of the key issues in tissue regeneration of these wounds is the controlled revascularisation of the epidermal tissue as well as the minimization of scar tissue formation. It is widely known for textile implant materials, that tissue formation and vascularisation depend on the size and distribution of pores and fibers. It is believed, that an arrangement of pores of different orders of magnitude, ranging from 1µm to 1000µm (see figure 1 E, F) will favour tissue ingrowth and the formation of new blood wessels and capillaries as it was demonstrated for implanted angiopolar cell carriers [5]. Embroidery technology was considered to achieve a 3-dimensionally structured textile architecture that combines different kinds of pores for directed angiogenesis and stiff elements for local mechanical stmulation of the wound. PET multifilament yarns of different texturations were used for the basic fabric and polyamide (PA) or PET monofilament yarns of various fiber diameters (100µm to 500µm) were used for the stiff knots between the macropores (see figure 1 F).

In its current application, the embroidered textile layer is combined with a spacer fabric as middle layer and an absorbant wound compress as top layer. The three textiles are assemled by ultrasonic welding. This wound dressing is currently investigated in first clinical trials for the treatment of patients with chronically non healing wounds (ulcus cruris).

MECHANICAL BEHAVIOUR OF EMBROIDERIES

Mechanical properties of medical fabrics change upon implantation or in vitro seeding with cells. In knitted and woven textiles, mechanical deformation of the textile structure first occurs as a relative displacement of yarns in the intermeshing region. Subsequently yarn bending and direct yarn stretching are observed. If the textile is implanted or used as a scaffold, different forms of stiffening are observed. Ingrowing cells and extracellular matrix deposition transform the yarns into bundels with higher bending stiffness. Simultaneously friction between yarns increases, caused by blocking of textile bonds. Both effects will considerably increase the fabric stiffness [6]. Furthermore, in highly strained textiles, local deformations and relative movements in the interlock regions might damage ingrowing tissue leading to an increased inflammatory host response.

For different applications, it is desirable to have a textile material, that does not alter its mechanical behavior when tissue grows in and thereby forms a vital-avital composite. It is believed, that due to their mechanical behavior, embroideries offer interesting possibilities for medical textile design. In contrast to the described textile behaviour, embroidered textiles are built up from defined stitches which do not allow relative movement of yarns through interlocks. Mechanically, this system can be described as a framework of beam elements that are connected by stiff knots. Therefore, the deformation depends on the distribution of knots and on the stiffness of the connecting beams, i.e. yarns. The mechanical behaviour can be 'tailored' by locally

integrating stiff elements such as monofilaments or by increasing the number of stitches per area.

In a comparative experimental study the influence of ingrowing tissue on the mechanics of the thereby formed vital-avital composite has been investigated. An interlock knitted fabric has been compared to the embroidered fabric described in example 2. A gelatin matrix (5%) has been used to simulate the ingrown tissue. Uniaxial tensile tests were carried out at a strain rate of 0.6 [mm/min]. The results shown in figure 2, suggest, that the embroidered textile does not undergo a stiffening, whereas in the knitted fabric a raise of tensile force (100% at a strain of 10%) is observed. This shows that due to the specific structure of the embroidery a stiffening effect could be prevented. This first result proves the working hypothesis, that embroidered textiles behave differently then most of the textiles that are currently used in medical applications.

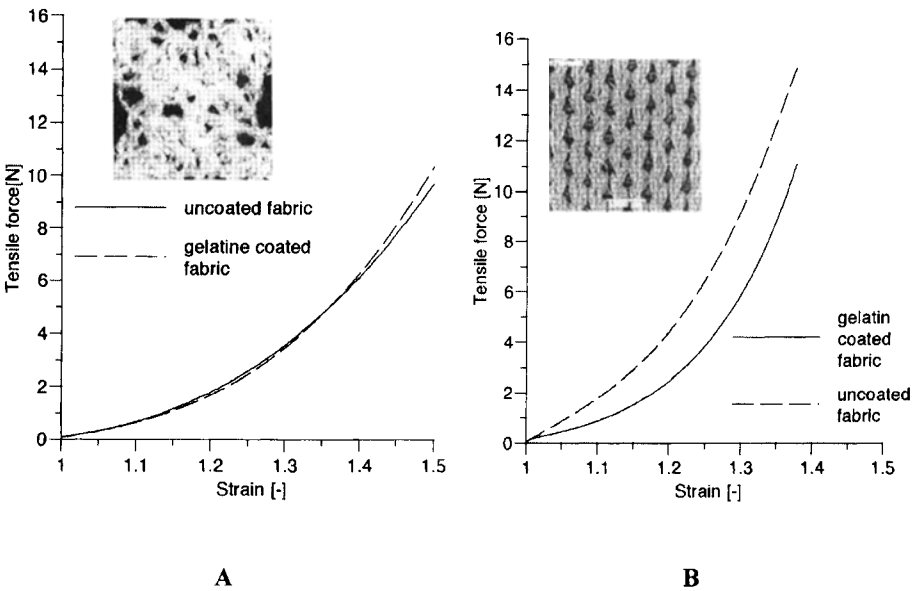

Figure 1. Mechanical behavior of gelatine coated and uncoated embroidered textile (A) in comparison with a knitted interlock fabric (B).

CONCLUSIONS

It is assumed that embroidery technology offers interesting possibilities for the development of tissue engineering scaffolds and medical textiles. Local variation of yarn material allows to build up degradable-nondegradable composites, to locally introduce hollow fibers for the supply of nutrients in bioreactor systems or to reinforce load induction areas in mechanically stressed textiles. Furthermore, control of mechanical anisotropy and local porosity can be realized in embroidered textiles. Since the textile can be designed like a framework of beams with desired local stiffness it may be possible to develop fabrics for medical applications with optimal compliance matching to the host tissue. Some possible applications of embroidery technology in medical textiles are summerized in table 1.

Embroidery feature	Effect	Possible application
Local introduction of different yarns into a basic fabric	• Composite of degradable-nondegradable fibers	• Tissue engineering scaffolds • Hernia mesh implants [3] • Integration of drug release systems
	• Placement of hollow fibers onto a basic (textile) membrane	• Nutrition supply for scaffolds in bioreactors of bioartificial organs
	• Local variation of stiffness using monofilaments or yarns with higher modulus	• Design of force induction areas in ligament protheses • 'Tailoring' of mechanical properties of the implant
Local variation of stitch density within the fabric	• Control of 'porosity'	• Tissue engineering scaffolds
	• Control of mechanical properties	• Implants which favour directed angiogenesis [5]
	• Influence on local tissue for mation, e.g. vascularisation	• Compliance matching in load bearing implants • Design of angiopoplar wound dressings

Table 1: Overwiev on possible applications of embroidery technology in medical textiles.

Future work will concentrate on the mechanical characterization of embroidered textiles and on assesment of biocompatibility of the embroidery process including optimization of cleaning procedures. It is assumed, that the potential of embroidery technology can be exploited either to create new textiles or to modify existing textiles, e.g. by locally integrating yarn material. This will allow to improve load bearing textiles and create effects for mechanical stimulation of the host tissue leading to new textiles with 'tailored' mechanical and structural properties

ACKNOWLEDGMENTS

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REFERENCES

1. Wintermantel, E., Mayer, J., Blum, J., Eckert, K.-L., Lüscher, P., Mathey, M., 'Tissue engineering scaffolds using superstructures', *Biomaterials*, 1996 **17** 83-92.

2 Klinge, U., Conze, J., Klosterhalfen, B., Limberg, W., Obolenski, B., Ottinger, A.P., Schumpelick, V., 'Alteration of abdominal wall mechancis after mesh implantation', *Langerbecks Archiv for Surgery*, 1996 **381**(6), 323-332.

3 Klinge, U., Klosterhalfen, B., Müller, M., Anurov, M., Öttinger, A., Schumpelick, V., 'Influence of polyglactin-coating on functional and morphological parameters of polypropylene-mesh modifications for abdominal wall repair', *Biomaterials* 1999 **20** 613-623.

4 Wan H., Williams R.L., Dohetry P.J., Williams D.F., 'A study of cell behaviour on the surfaces of multifilament materials', *Journal of materials Science, Materials in Medicine* 1997 **8** 1997 45-51.

5 Wintermantel E., Cima L., Schloo B., Langer R., 'Angiopolarity of cell carriers. Directional angiogenesis in resorbable liver cell transplantation devices', in: R. Steiner, B. Weisz and R. Langer, eds., *Angiogenesis: Principles-Science-Technology-Medicine*, Birkhäuser Verlag Basel, 1992 331-334.

6 Joop de Haan, 'Structure-property relations in plain weft-knitted fabric reinforced composites (KFRCs) preparing for load bearing implants: experimental study and beam model approach'; Diss ETH No. 13042, 1999.

25. Tissue Engineered Synthetic Scaffolds for Tissue Repair - A Textile Approach to Implant Design

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Introduction

Tissue engineering is an emerging interdisciplinary field that applies the principles of biology and engineering to the development of viable substitutes that restore, maintain or improve the function of human tissues. This form of therapy differs from standard drug therapy in that the engineered tissue becomes integrated within the patient and has the potential to offer a permanent and specific cure for the disease state. Although cells have been cultured outside the body for many years, it has recently been possible to grow complex three-dimensional tissue constructs in the laboratory *in vitro* to meet clinical needs. Many textile designs have been produced to reproduce the fibrous architecture of tissues that need augmenting (supporting) or replacing (prosthetic) in the human body. Tissue engineering concepts of producing a lattice for the ingrowth of cells *in vivo* to lay down the appropriate matrix have been used very successfully for the skin, and for the repair of the fascia in hernias. The concept has also been utilised in the development of a cartilage support matrix that has seventeen years of clinical experience in various joints in the body. The position of potential tissue engineered materials in the overall picture of medical related textiles is shown in table 1.

Design parameters

The approach used by researchers has been to assume that cells and their accompanying matrix needs a scaffold to enter, adhere to and proliferate in an ordered manner. The three features of the tissue engineered scaffold are the overall architecture and porosity, the fibre morphology and the surface chemistry.

Textile mesh knitted monofilament or multifilament yarns made of permanent or resorbable polymers have produced the most common three-dimensional scaffolds used in tissue repair. Depending on the applications, their characteristics can be altered to, say have high tensile strength (such as a ligament prosthesis), suture retention abilities (hernia reinforcement) or an architecture and porosity that is similar to the structure being replaced (articular cartilage). There is a move to more "tension-free" surgery in the repair of the hernia wall and, as a consequence, the tensile strength of the mesh is not of prime consideration, but the retention of securing sutures is important. The porosity of the scaffold determines the "flow" of the repair matrix material and the laying down of the initial scar material leading to a fibrous repair. Animal experiments using a textile mesh knitted multifilament yarn of polyester (Mersilene™) clearly show that a highly porous mesh with

holes at least 1 mm wide is undesirable for integration of the repair, and that a much smaller and uniform hole with still a high porosity (>80%) are much more preferable conditions for a proliferative repair.
Fibre surface morphology is another repair-inducing factor that is relevant to the repair process. The main repair fibre producing cells (Fibroblasts) appear to prefer their processes to attach to a rough fibre surface rather than a smooth surface. These are seen on carbon fibres very clearly as these fibres have longitudinal grooves during the production process of spinning.
The fibre chemistry relating to the leaching out of substances with time and the pH of the immediate environment around the fibre will dictate the chemical response of the repair tissue. An electronegative environment is inducive to repair and whether the surface tension produces a highly hydrophobic material such as PTFE with poor cellular attachment.
In our experience, carbon fibre has most of the three attractive features to tissue regeneration described if produced to the optimum design for the application. The three applications in which carbon fibre pads have been produced are: For the reinforcement of the fascia in the inguinal hernia; as a tissue regeneration implant for pressure sore prevention; and for the biological resurfacing of damaged articular cartilage.

Hernia reinforcement

The specifications of the ideal implant were determined when the surgical technique was established. The mechanical properties of the implant are dependent on the method of implantation in the area of the hernia. The current surgical practice was to produce an implant that would be sandwiched between two layers of fascia that could be apposed above and below the implant in a "tension-free" manner. The ideal characteristics were: that the implant should be able to be held *in situ* by peripheral sutures, resist the possibility of loading under biaxial tension without breaking up during the very early post-operative period due to say coughing or lifting; and to produce an organised fibrous tissue response quickly with minimal inflammation.

A densely woven mesh of carbon fibres in a continuous multifilament yarn was produced, the yarn bundles containing as many as 1,000 carbon fibres. Although the carbon fibres are two orders of magnitude in diameter larger than collagen fibres that constitute the fibrous element of the repair matrix (Fig 1), the porosity of the implant especially at the first interface with the repair matrix allows the fibrous structure to invade the implant with ease. The top and bottom surfaces of the woven mesh are covered with a non-woven layer of carbon fibres and the three layers are attached by a double acting needling process that allows interdigitation of the nonwoven layers with the central woven mesh (Fig 2). The two outer surfaces then present an interface highly porous scaffold with the repairing matrix for the ingrowth of cells/vascular and fibrous structures for total integration at the wound site. The strong central woven mesh allows the passing of sutures and their retention and has the biaxial tensile strength to resist sudden tensile loads that may occur before the full integration of the repair material.

Pressure sore repair

The implants are of similar structure to the hernia repair fabric but have more alternate layers of woven and nonwoven meshes to make a thicker pad (5 or 10 mm thick with the thicker pad having a 5 mm thick nonwoven section). The thicker pads have been used for the repair of the fascia overlying the ischial tuberosities and the larger thinner pads over the trochanteric area.

Articular cartilage resurfacing

Carbon fibre pads which are placed in defects with the subchondral bone have a much looser woven central layer so that the high porosity is maintained throughout the thickness of the implant (Fig 3). There is not a need to have any inherent strength in this situation as the implants are used purely for an inert scaffold. The collagen framework of articular cartilage rises from the subchondral bone into continuous arcades. The repair tissue ingrown into the carbon fibre implants may not reproduce this arcadial arrangement. However, the repair tissue when integrated forms a solid compliant plug of a composite fibrocartilage with the majority of the surface fibres in the plane of the surface providing a firm frictionless layer for the apposing surface to articulate with.

Conclusions

The science of tissue engineering as applied to tissue repair in three applications highlight the features of importance when utilising a textile approach to designing implants. The use of knitted polyester meshes with pore sizes many orders of magnitude than the repair matrix requires can result in a tissue response which is inadequate(Fig 4). Pore sizes of between 10-50 μm and an overall porosity of 85-90 percent with multifilament fibre yarn with fibre diameters of 1-10 μm appear the most ideal for the encouragement of a repair matrix ingrowth. Experience with carbon fibre in these forms appears to provide the optimal environment for the regeneration of tissue in the hernia, subcutaneous and intra-articular sites. The main weight bearing element of the carbon fibre pads are woven layers of mesh with nonwoven layers on the surfaces. The individual carbon fibres appear to present an attractive surface, morphologically and chemically, to the attachment of fibroblasts which eventually produce a collagenous framework within the implant scaffold at the sites described.

Bibliography

Freed,L E and Vunjak-Novakovic,G. (1995) Tissue Engineering of Cartilage. In "The Biomedical Engineering Handbook" Ed J.D.Bronzino, Pub CRC Press (ISBN 0-8493-8346-3) pp1788-1806.

King,M.W, Soares, B.M and Guidoin, R (1996) The chemical, physical and structural properties of synthetic biomaterials used in hernia repair. In "Prostheses and Abdominal Wall Hernias" Ed R Bendavid, Pub R G Landes, Austin,Texas. Chapter 15, pp 191-206.

Klosterhalfwen,B, Klinge, U and Schumpelick, V (1998) Functional and morphological evaluation of different polypropylene-mesh modifications for abdominal wall repair. Biomaterials, **19**, 2235-2246.

Minns,R.J. (1996) Structural and mechanical aspects of prosthetic herniorrhaphy. In "Prostheses and abdominal wall hernias" Ed R Bendavid, Pub R G Landes, Austin, Texas. Chapter 11, pp123-137.

Minns, R J, et al (1982) An experimental study of the use of a carbon fibre patch as a hernia prosthesis material. Biomaterials, **3**, 199-203

Minns, R J. et al (1993) The repair of inguinal hernias using carbon fibre patches; a five year follow-up. Clin Materials, **14**, 139-144.

Minns, R J and Sutton, R A. (1991) Carbon fibre pad insertion as a method of achieving soft tissue augmentation in order to reduce the liability to pressure sore development in the spinal injury patient. Br J Plastic Surg. **44**, 615-618.

Ward, R and Minns, R J. (1989) Woven carbon fibre patch versus Dacron^{R} mesh in the repair of experimental defects in the lumbar fascia of rabbits. Biomaterials,**10**, 425-428.

Table 1

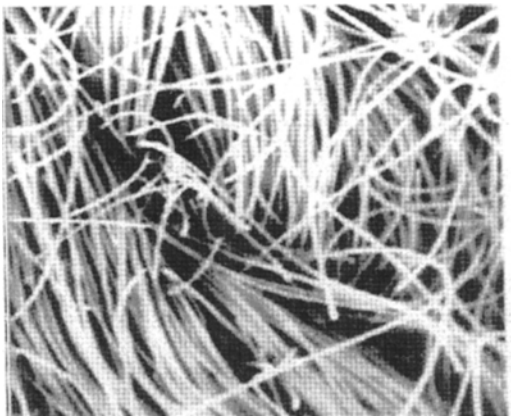
MEDICAL TEXTILES

Applications	Growth/Decline
Filters for clean air operating systems and barrier nursing wards down to 0.2um	Growth: For disposable materials
Extracorporeal filtration/exchange Dialysers	Growth for disposable
Gowns: move to disposable for high risk patients	Decline for woven washables
Incontinence pads with absorbency and odour reducing agents	
Drapes: probably move to disposable paper easy to cut, can have adhesive strips attached	As above
Heamostats: swabs, still woven	Decline as more day 'keyhole' surgery performed
Heamacell woven biodegradable with fibrin attached	Growth for above reason

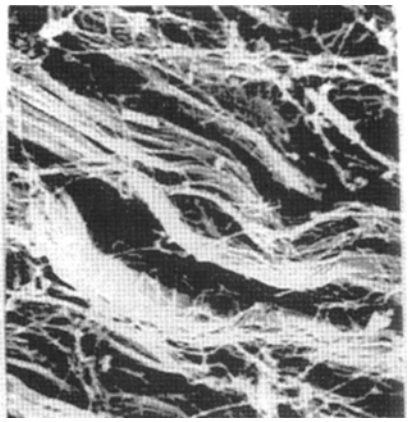
Tissue engineered examples

Tissue Engineered structures to allow seeding of cells before or after implantation in all aspects of soft tissue repair

Dressings: on skin, woven, drug impregnated for slow drug release	Growth- leg ulceration management Pressure sore management (incidence declining)
Semi implantable collagen based woven	Possible growth to reduce need for nursing input
Implants: general surgery- herniae abdominal reinforcement in plastic surgery(burns) augmentation	Growth, in particular biodegradable scaffolds of woven collagen. Able to compress and reform shape *in vivo* for laparoscopic surgery.
Orthopaedics: cartilage repair ligaments	Growth in woven scaffolds

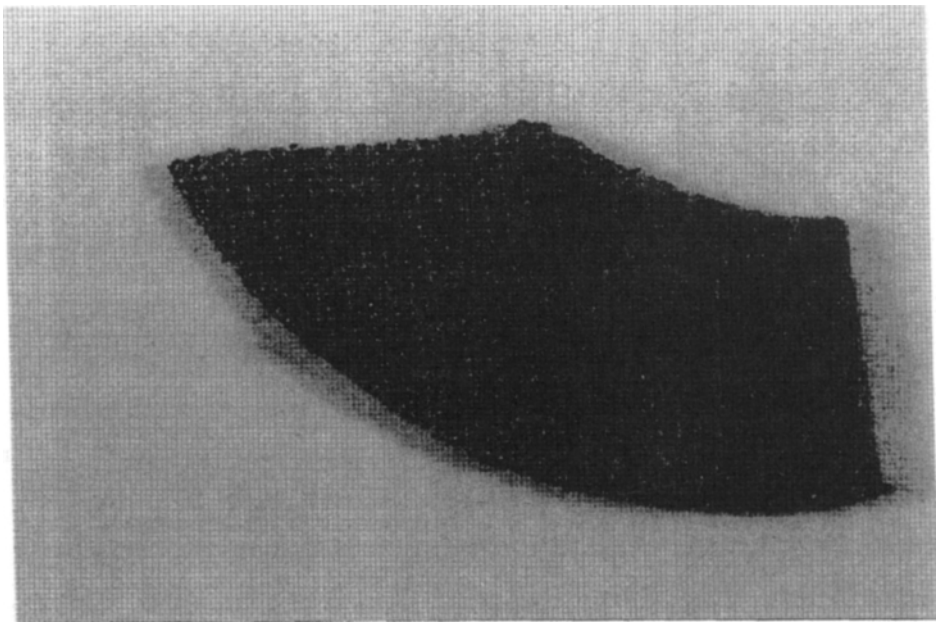


Carbon fibres(10 μm dia)



Herniated fascia fibres(0.1 μm dia)

Figure 1



Sample of hernia fabric revealing the woven core on the left

Figure 2

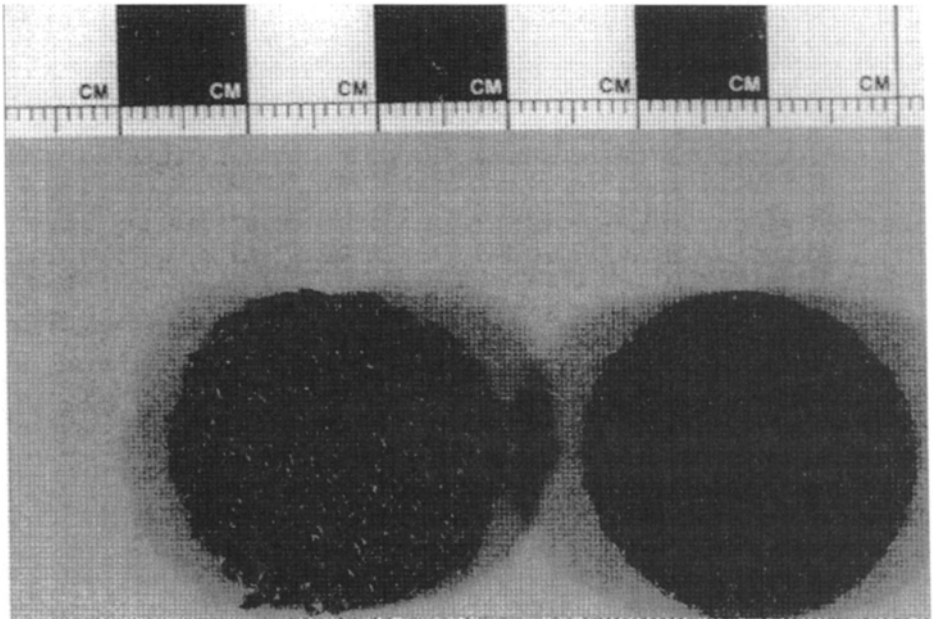


Figure 3. Carbon fibre pads for articular cartilage resurfacing showing the loosely woven yarn midsection on the left sample.

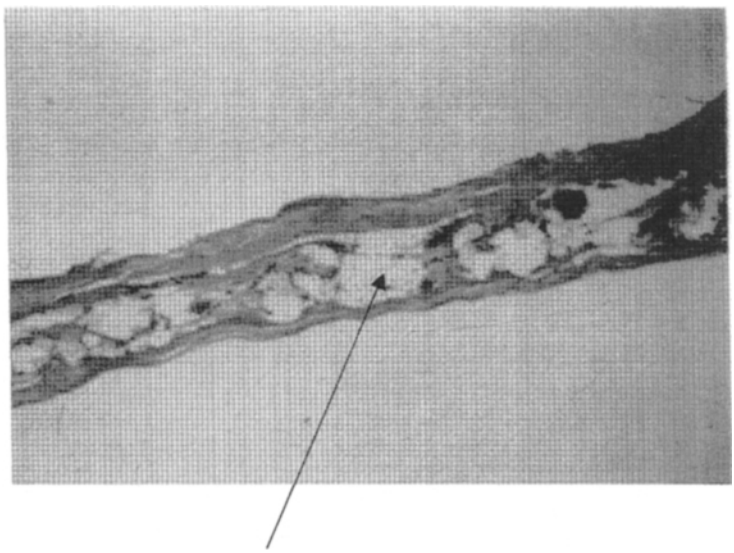


Figure 4. Histology of a multifilament polyester yarn (Mersilene^{TM}) after 12 weeks implanted in the rabbit showing a flimsy fibrous response.

Session 6: Test methods

26. Pitfalls of Statistics in Clinical Trials Design

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INTRODUCTION

The majority of papers published in medical journals will include some form of statistical analysis. Emerson and Colditz estimated in 1983 that 70% (1) of the original articles published in the New England Journal of Medicine used some form of statistical analysis. Campbell and Machin (1) identified a similar proportion of papers containing statistical analysis in the British Medical Journal and the Lancet.

A basic understanding of statistical principles is therefore required to allow interpretation and critical appraisal of the content of these papers. It is crucial that readers are able to distinguish between good studies and bad studies in order to verify whether the conclusions of a trial are valid and to understand the limitations of studies. Felson et al (2) reported in 1984 that the proportion of statistical errors in one journal in 1967 and 1982 were 60% and 66% respectively, which highlights the importance of having a basic understanding of statistical principles.

WHY USE STATISTICS?

Statistics are used so frequently in the analysis of biological and medical data due to the variable nature of the data collected. A chemical reaction is generally guaranteed. For example, if you repeatedly put blue litmus paper into an acidic solution, it will turn red 100% of the time, not 95% of the time. This can rarely be said for the collection of results from human subjects though. A prime example is with the development of disease as a result of smoking. Most people now accept that smoking causes lung cancer and heart disease. Many people though will know of someone who has smoked 20 cigarettes a day for 40 years with apparently no ill effect. Statistics is a tool that can be used to decide whether an observed variable should be ascribed to chance or whether it can be assumed to be due to a real effect. It allows you to ascribe a probability to a given outcome. In the case of smoking, it allows you to make a statement about what the probability is of developing lung cancer and heart disease if you smoke.

TRIAL DESIGN

A well-designed trial that is poorly analysed can be rescued by reanalysis, but a poorly designed trial can not be rescued by even the most sophisticated statistical techniques. In fact, it is considered unethical to conduct a badly designed trial on human subjects that will not produce data that is credible or sufficient to achieve the aim. It is therefore crucial that adequate time is spent on planning before a trial is started. A statistician should therefore be employed at the design stage of a trial to advise on the necessary sample size, confidence intervals and power of a trial.

Types of trial

Parallel Group Design

Subjects recruited to these trials are treated separately with either Product A or Product B.

Crossover Design

Subjects in these trials are treated with Product A and then Product B, or vice versa. This type of design requires fewer subjects than the parallel group design as subjects act as their own control. Care must be taken however to ensure that a sufficient washout period is given in-between treatments to guarantee that any residual effects are eliminated. This trial design should only be used when the effects of the trial products develop rapidly and are completely reversible. It is also only appropriate for subjects who have a stable and chronic disease and for subjects whose condition is not likely to deteriorate rapidly whilst in the trial.

Factorial Design

Subjects in these trials are treated with all combinations of the trial products (i.e. Product A + B, Product A alone, Product B alone or neither Product A nor Product B).

Superiority Trial

The aim of these trials is to confirm one products superior efficacy over another. The comparator product could be an existing product or a placebo.

Equivalence Trial

The aim of these trials is to confirm that two (or more) products are equivalent in efficacy. They are often conducted when the use of a placebo is considered unethical. An equivalence trial is not conservative in nature (3), and so many flaws in the design or conduct of the trial will tend to bias the result towards a conclusion of equivalence. Subjects who withdraw or dropout from treatment tend to bias the results towards showing equivalence. It is therefore important to take careful steps to ensure the number of subjects lost due to non-compliance, protocol violation, withdrawals and losses to follow up are minimised as much as possible to reduce the impact on the analysis.

Sample size

The sample size must be large enough to achieve the aim of the trial, but the smallest possible to achieve the aim. It is unethical to enter more subjects into a trial than is necessary to achieve the aim, but likewise, it is also unethical to include subjects in a trial if insufficient data is collected to allow adequate analysis.

The sample size for phase III trials is usually chosen based on the primary efficacy objective. For such trials, an estimation of the efficacy of the trial products should be known. If the trial is an exploratory trial though (e.g. on a new chemical entity), there may be no data on which to estimate the product efficacy. As such, the product should be tested on only a small sample population to collect some provisional data on efficacy.

When choosing the sample size, it is important to determine what confidence limits and power you want the trial to have (i.e. what certainty you want to have of avoiding type I and type II errors).

Population

In the early stages of development of a product, you may wish to maximise the chance of observing specific clinical effects of interest, and hence may choose to study a very narrow sub-group of the patient population. Once the development of a product has progressed to phase III clinical trials however, the patient population used in a trial should more closely match the intended users. For this reason, the inclusion/exclusion criteria are usually relaxed for later stage clinical trials.

Clinical trials can not mirror the use of a product out of a trial situation, but affects of being in a trial should be minimised as much as possible and where necessary discussed in the paper. For this reason, the study population should match the population of the intended users as far as possible.

Techniques to avoid bias

Blinding

The double-blind trial is considered the "gold standard" in clinical trials. In such situations, neither the investigator nor the subject is aware of which trial product is being used. As the appearance or the dosing interval of the products in the trial may be different, (e.g. one product may be in tablet form while the other is in capsule form), it may be necessary to conduct a double-dummy trial. In these trials, the subject is given a placebo product in addition to the test product to conceal which product they are being treated with. For example, one group of subjects may be given active tablets and placebo capsules While the other group is given active capsules and placebo tablets.

The design of double blind double-dummy trials must be considered carefully to avoid making a treatment schedule so arduous that it demotivates the trial subjects and hence increases the non-compliance, withdrawal and dropout rates.

Where a double blind trial is not possible or ethical (e.g. in trials comparing medication with surgery), it may be necessary to conduct a single blind trial. As in most cases the investigator will be the person that knows what has or will be prescribed, care must be taken to avoid the investigator selecting subjects that he/she feels would be best suited to a particular treatment.

Randomisation

Randomisation can benefit from being blocked (e.g. balanced per centre) and/or stratified (e.g. for wound size). Randomisation should be conducted in such as way so that the investigator recruiting subjects into the trial does not know what the next assigned product will be. This is important to avoid bias (either deliberate or unintentional), whereby an investigator may recruit subjects into the product group that they feel is most appropriate.

SUMMARISING DATA

Types of Data

Data produced from clinical trials can be grouped into certain types:

Quantitative

Continuous interval: e.g. height, weigh, blood pressure.
Discrete interval: e.g. number of children, number of attacks per week.

Categorical

Ordinal (ordered categories): e.g. better/same/worse, disagree/neutral/agree.
Nominal (unordered categories): e.g. male/female, alive/dead, blood group.

It is often easier to summarise categorical variables, so quantitative variables are often converted to categorical ones for descriptive purposes by using cut-off points (e.g. height can be grouped into small, medium and tall). This makes the data easier to handle but looses some of its sensitivity. Statistical analysis should therefore always be done on ungrouped data where possible.

The average

A summary of the average or typical value of a group of measurements is commonly known as a measure of central tendency. The three measures of central tendency used for different types of data are the mean, the median and the mode.

Mean

The mean is calculated simply by dividing the sum of the measurement values by the number of values. The use of the mean to describe the central tendency of data should be restricted to continuous interval data (4). It is often also used to describe central tendency in discrete interval data (e.g., the average number of children per family is often quoted as being 2.4). As this has no real meaning, it may be more appropriate to use an alternative form of measure for this data (e.g. the mode).

Median

This is the middle value of a set of numbers if all values are placed in numerical order. In cases where the number of values is even, the median is the $\frac{1}{2}(n+1)^{th}$ value. It is most commonly used to describe central tendency for discrete interval data or ordinal data, but may also be used to describe continuous interval data (4).

Mode

This is simply the most frequent value or category. It can often be easily spotted by "eyeballing" the data. A data set will have several modes if a number of values occur with the same frequency. The mode can be used with all types of data but is most commonly used with nominal data (4) to describe what is known of as the modal category.

All three of the methods used to describe central tendency can be used inappropriately. The mean for example can be greatly effected by outlying values. Just one very high or low value, can shift the mean value significantly. In such cases, it might be more appropriate to use the median (middle) value. Likewise, the use of the median or mode

value to express the central tendency in data that is significantly skewed is also inappropriate.

The inappropriate use of the above methods to describe central tendency could be accidental or could be quite deliberate if the misleading expression of central tendency is in the author's favour. Therefore, whenever central tendency (or an average value) is given, it should always be supported with an indication of the spread (or variability) of the data set.

Variability of data

It is not only important to describe the scatter or variation among data for descriptive purposes, but also to allow the selection of the most appropriate statistical method to test the hypothesis.

The normal distribution is the theoretically perfect frequency curve in which the mean, median and mode all coincide in the centre to form a symmetrical bell shape. A data set that conforms to the normal distribution can be described completely by two parameters, the mean and the standard deviation. Such data is described as parametric.

Calculations based on data that has been incorrectly assumed as having a normal distribution are inappropriate, as the calculations are very sensitive to outlying values (5). Therefore, before any analysis is conducted, the data should be tabulated or plotted to get an idea of its variability and distribution. A simple way to do this for a small data set is to tabulate the results into a stem and leaf plot (see figure 1). Once the data is tabulated in this way, it is much easier to judge whether or not it conforms to the normal distribution.

Symmetry of data

The symmetry of data is also an important characteristic of its distribution that should be considered before analysis. This is often known as the degree of skew. Two sets of data could have the same mean and standard deviation but still be completely different. One set could be positively skewed and the other negatively skewed. Statistical analyses based on the mean and standard deviation alone (e.g., the students t-test) would be inappropriate for data that is significantly skewed.

Measurement values: 0.6, 2.6, 0.1, 1.1, 0.4, 2.0, 0.8, 1.3, 1.2, 1.5, 3.2, 1.7, 1.9, 1.9, and 2.2.

Write the "stems" (the number before the decimal place) in order down the page, and then add the "leaves" (the number after the decimal place) as they come:

Stem	Leaf
0	6 1 4 8
1	1 3 2 5 7 9 9
2	6 0 2
3	2

Stem and leaves "as they come"

Stem	Leaf
0	1 4 6 8
1	1 2 3 5 7 9 9
2	0 2 6
3	2

Ordered stem and leaf plot

Figure 1: Stem and leaf plots

COMMON ERRORS

Type I error

Statistical testing is often based on the null hypothesis (the null hypothesis being that there are no differences between two populations/data sets). What does "no difference" really mean though? Chance alone will ensure that there will be some difference between the sample means of two populations. Consequently, limits are set within which samples are regarded as have no significant difference. This is typically set as twice the standard error of the difference between the means and will give a 95% confidence interval. Any mean outside this range is regarded as being from a separate population. On average, 1 in 20 times the conclusion that the populations are different will be wrong. To reject the null hypothesis when it is true is to make what is known of as a type I error. The level at which a results is declared significant is called the type I error rate.

A range of not more that two standard errors is often taken as implying "no difference", but a range of three standard errors (or more) could be used to reduce the chances of a type I error.

Type II error

When two populations are compared, and the analysis gives a non-significant result (i.e. the null hypothesis is not rejected), this does not mean that the two samples tested have come from the same population – it simply means that you have failed to prove that they are different. Failure to reject the null hypothesis when in fact there is a difference between the two populations is known as a type II error. The type II error rate gives you the power of a trial. The most common reason for type II errors is that the trial is too small (6).

Incorrect analysis

In order to be able to make a statement about certain differences between populations, or that a certain correlation between variables can be generalised to the whole population, the appropriate inferential statistical test must be applied. Inferential statistics gives a means of determining how reproducible the results of a trial are by applying a probability to the observed variable. The smaller the probability ("p" value), the less the likelihood that the observed variation occurred by chance.

Numerous statistical tests are available. The selection of the most appropriate statistical test is determined by the following considerations (7):

1 The type of data produced from the trial (nominal, ordinal, continuous interval, discrete interval).
2 The number of groups used in the observation.
3 Whether the measurements were obtained from independent subjects or from related samples, such as those involving repeated measurements of the same subjects.
4 The assumptions involved in using a statistical test (such as the expected distribution of the data set).

Additional criteria may require consideration when selecting the most appropriate statistical test such as sample size (e.g. if $n < 30$ the student t-test should be used instead of the z test – simple comparison of difference between means).

A number of tables exist to allow easy selection of the most appropriate statistical test (6, 7).

Tests that are appropriate for analysing categorical data are called non-parametric or distribution free tests. The tests that are appropriate for analysing interval data are called parametric tests. The parametric tests (e.g. z, t or F) require that certain assumptions (such as normality or equal variance) be valid for the populations from which the samples are taken. The non-parametric tests (e.g. χ^2, Mann-Whitney U), require few, if any assumptions about the underlying population distributions.

Incorrect interpretation

In a trial that is very large, even small differences can become statistically significant. For example, a clinical trial comparing two hypertensive agents in 500 subjects may show a statistically significant difference in blood pressure after treatment with the two different products of 2mmHg. As such, a paper on the trial could correctly quote that "A was significantly better than B", without any mention of how small the treatment difference was. Such a small treatment difference however is probably of no clinical importance to the subject.

Alternatively, a very small trial could highlight a large difference between two treatments, without showing a statistical significance. For example, in a trial of 15 subjects comparing a placebo with a hypertensive agent, the difference in blood pressure could be shown to be 15mmHg. As the trial population was so small though, this may not be shown to be statistically significant. The clinical importance of the results from such a trial should not however be overlooked. This situation could arise in a trial studying a rare condition where it may not be possible to recruit a large number of subjects. A paper should not be dismissed as unimportant simply because there are no statistically significant findings.

CRITICAL EVALUATION OF RESEARCH

Before a paper is published in a reputable journal it will be critically evaluated by experts in the area for errors or problems. Often problems will remain unidentified though. Ultimately, therefore it rests on the readers of clinical papers to read them in a critical way. The aim of critical evaluation is to identify the strengths and weaknesses of a trial in order to allow an informed decision to be made about any changes that should be made to medical practice.

ICH TOPIC E9 - STATISTICAL PRINCIPLES FOR CLINICAL TRIALS

This guideline has been written primarily as an attempt to harmonise the principles of statistical methodology applied to clinical trials for marketing applications submitted in Europe, Japan and the United States.

The guideline is intended to give people who are planning to conduct a clinical trial direction on the design, conduct, analysis and evaluation of trials. The guideline focuses on statistical principles rather than on specific statistical procedures or methods.

The guideline covers the considerations that should be made for overall clinical development, trial design, trial conduct, data analysis, evaluation of safety and tolerability and reporting, and should be used as a starting point for anyone considering conducting a clinical trial.

REFERENCES

1 M J Campbell, D Machin, *Medical Statistics – a common-sense approach*, Chichester, John Wiley & Sons, 1994.

2 D T Felson, L A Cupples, R F Meenan, "Misuse of statistical methods in arthritis and rheumatism: 1982 versus 1967-78", *Arthritis and Rheumatism,* 1984 **27** 1018-1022.

3 Note for Guidance on Statistical Principles for Clinical Trials, ICH Topic E 9, CPMP/ICH/363/96.

4 S Banks, "Analysis of quantitative research data: Part 1", *Professional Nurse*, 1999 **14**(9) 634 – 637.

5 A Wiles, D Chanter, "Statistics", *Clinical Research Manual*, Euromed Communication Ltd, 1997, 16.1-16.45.

6 T D V Swinscow, *Statistics at Square One*, London, BMJ Publishing Group, 1996.

7 S Polgar, S A Thomas, *Introduction to Research in the Health Sciences*, London, Churchill Livingstone, 1995.

27. The Drug Tariff and its Relevance to Medical Textiles

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The Drug Tariff and Its Relevance to Medical Textiles

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The Drug Tariff and Its Relevance to Medical Textiles

Issues Addressed Here:

- What is the Drug Tariff
- Where Does it fit within the NHS
- Who uses it and why
- How are products listed in the Drug Tariff
- How are industry's interests represented

What is the Drug Tariff - Parts I to XVIIIC

Part I Requirements for the Supply of Drugs, Appliances and Chemical Reagents

Drugs must comply with relevant standards or formulae unless the prescriber indicates otherwise

Only Appliances and *Reagents* listed in Part IX are available on NHS prescription and they can all be prescribed by nurse practitioners unless otherwise annotated

Part II Requirements enabling payment to be made for Drugs, Appliances and Chemical Reagents

- Rules for calculating prices and instructions to contractors on endorsing prescription forms
- Rules on quantities to be supplied
- Reimbursement
- *Discount*
- Calendar Packs
- Broken Bulk
- (Patient Packs)

Part IIIA Professional Fees (Pharmacy Contractors)

Details of fees payable per prescription together with instructions for exceptional cases

Part IIIB Scale of Fees (Appliance Contractors)

Related to appliance type

Part IV Containers

Details of types of containers to be used and fees allowable

Part V Deduction Scale

Rates of deductions to be applied to total cost of products supplied

Part VIA Payment for additional professional services

These apply where all the following conditions are met:

- the pharmacy produces a practice leaflet;
- the pharmacist displays up to 8 health promotion leaflets;
- the contractor keeps patient medication records.

Part VIB Scale of on-cost allowances (Appliance Contractors)

Part VII Drugs with Commonly Used Pack Sizes

Part VIII Basic Prices of Drugs Covered by Part II Clause 8a

Part VIII

- NIC to be reimbursed
- PPA calculate
- Secretary of State agrees to entry or changes
- Basic Price of Drugs

Part VIII (continued)

- **Category A**
  - Common item - weighted average
    - 2 wholesalers and 3 generic manufacturers
- **Category B**
  - Older preparations
- **Category C**
  - Commonly used - not qualifying for A mainly proprietaries

Part VIII (continued)

- **Category D**
  - Limited availability
- **Category E**
  - Dispensed extemporaneously

Part IX Approved List of Appliances - Notes and Technical Specifications

Part IXA Approved List of Appliances

Part IXB Incontinence Section including list of components and accessories

Part IXC Stoma Section including lists of components and accessories

Part IXR Approved List of Chemical Reagents & Appendix

Part X Domiciliary Oxygen Therapy Service

Part XI Rota Service

Part XII Essential Small Pharmacies Scheme

Part XIII Payment in Respect of Pre-registration Trainees

Part XIVa Advice to Residential Homes

Part XIVb Patient Medication Records

Part XV Borderline Substances

Part XVI Prescription Charges

Part XVII Preparations which may be prescribed by dentists

Part XVIIA SofS List Preparations prescribable on FP14 or FP10d

Part XVIIB SofS List Preparations prescribable on FP10 (CN)

Part XVIIIA Drugs and other substances not to be prescribed under the NHS Pharmaceutical Services

Part XVIIIB Drugs to be prescribed in certain circumstances under the NHS Pharmaceutical Services

Part XVIIIC Guidance on the Therapeutic Groups of Drugs that are restricted under the NHS Pharmaceutical Services

Legal Standing of Part IX

Section 41 of the NHS Act 1977

- *A duty for health authorities to provide for the supply to persons in that area "proper and sufficient drugs and medicines and listed appliances which are ordered for those persons by a medical practitioner..."*

"Listed" means included in a list for the time being approved by Secretary of State for the purposes of this section

Legal Standing (2)

Regulation 18 of the National Health Service (Pharmaceutical Services) Regulations 1992 requires Secretary of State to compile and publish the Drug Tariff to include:

a) The list of appliances and chemical reagents for the time being approved by SofS for the purposes of Section 41

b) The prices on the basis of which the payment for drugs and appliances ordinarily supplied is to be calculated

Legal Standing (3)

Paragraph 43(1) of Schedule 2 to the National Health Services (General Medical Services) Regulations 1992 requires that GPs use the NHS prescription form to order drugs and appliances for reimbursement to be given.

Part IX of the Drug Tariff

Six sections:

1. Notes
2. List of Technical specifications
3. Part IXA - Appliances
4. Part IXB - Incontinence Section
5. Part IXC - Stoma Section
6. Part IXR - Chemical Reagents

PART IXa APPLIANCES

- Absorbent cottons
- Applicators, vaginal
- Atomisers, hand operated
- Bandages
- Breast reliever
- Breast shield
- Brushes
- Catheters
- Cellulose wadding
- Chiropody appliances
- Contraceptive devices

PART IXa APPLIANCES (continued)

- Douches
- Dressings
- Elastic hosiery
- Eye baths
- Eye shades
- Finger cots
- Finger stalls
- Gauzes
- Hypodermic equipment
- Inhalers
- Insufflators

PART IXa APPLIANCES (continued)

- Laryngectomy protector
- Latex foam, adhesive
- Lint
- Nipple shields, plastics
- Peak flow meters
- Pessaries
- Plasters
- Protectives
- Rectal dilators
- Stockinette
- Suprapubic belts

PART IXa APPLIANCES (continued)

- Suprapubic catheters
- Surgical adhesive tape
- Surgical sutures
- Syringes
- Test tubes
- Tracheostomy appliances
- Trusses
- Urinals, portable
- Urine sugar analysis set

PART IXb INCONTINENCE APPLIANCES

- Drainable dribbling appliances
- Incontinence belts
- Incontinence sheaths
- Incontinence sheath fixing strips and adhesives
- Leg bags
- Night drainage bags
- Suspensory systems
- Tubing and accessories
- Urinal systems

PART IXc STOMA APPLIANCES

- Adhesive discs/rings/pads/plasters
- Adhesive (pastes, sprays, solutions)
- Bag closures
- Bag covers
- Belts
- Colostomy bags
- Colostomy sets
- Deodorants

PART IXc STOMA APPLIANCES (continued)

- Filters/bridges
- Flanges
- Ileostomy (drainable) bags
- Ileostomy sets
- Irrigation/wash-out appliances
- Pressure plates/shields
- Skin fillers and protectives

PART IXc STOMA APPLIANCES (continued)

- Skin protectors
- Stoma caps/dressings
- Tubing
- Two piece ostomy systems
- Urostomy bags
- Urostomy sets

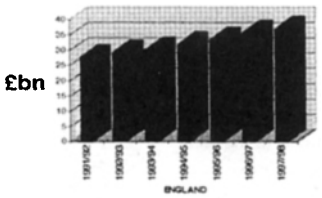
PART IXr - CHEMICAL REAGENTS

- Glycosuria Detection Tablets
- Ketonuria Detection Tablets
- Gerhardt's Reagent
- Ammonia Solution
- Sodium Iopodate
- Urine Detection Strips for
  - Glycosuria
  - Ketonuria
  - Proteinuria
- Blood Glucose Testing Strips

Examples of Generic Products in Part IX

- **Cotton Crepe Bandage BP**
- **Suspensory Bandage**
- **Wool Felt BP**
- **Absorbent Cotton Gauze**
- **Paraffin Gauze Dressings**
- **Belladonna Plaster**
- **Filmated Gauze Swab BP 1988 - non sterile**

Total NHS Expenditure

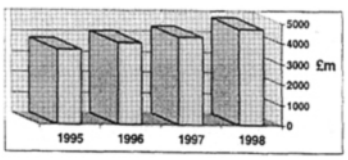


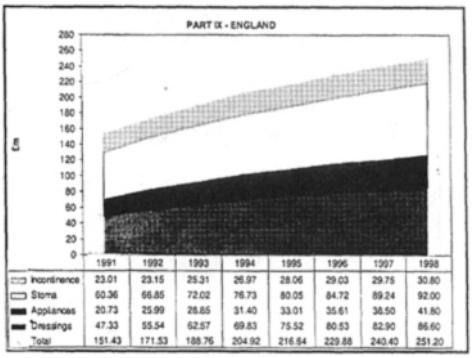
Drugs Bill as a Proportion of Health Expenditure

	1995	1996	1997	1998
Total NHS Bill (£m)	31,973	33,473	35,800	39,581
Total Drugs Bill (£m)	3680.6	4007	4270	4701.5
% of NHS Expenditure	11.51%	11.97%	11.93%	11.88%
Part IX (£m)	214.00	225.00	240.30	251.00
% of Drugs Bill	5.81%	5.62%	5.63%	5.34%

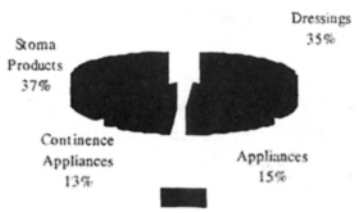
ENGLAND

DRUGS BILL - ENGLAND





Part IX England

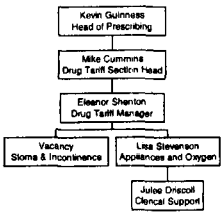


Who uses the Drug Tariff?

- *Manufacturers*
- *Clinicians*
- *Pharmacy Contractors*
- *Department of Health*
- *Prescription Pricing Authority*

The Application Process

Drug Tariff Organisation Chart



The Part IX Application Process

What to submit:

- Form DT1
- Declaration of Conformity if CE Marked
- Evidence of Compliance with external standards
- 3 Product samples Supporting evidence for entry price sought

Application Guidance Document

- Compiled by DTS in conjunction with ABHI and issued in 1995
- Medical Devices Directive prompted revised procedure
- 3 tests
  - Appropriateness
  - Safety & Quality
  - Cost Effectiveness

Role of Technical Standards

- Drug Tariff Specifications frozen from April 1995
- Industry play greater role in setting standards
- Standards may be used to indicate cost effectiveness in relation to similar products

Clinical Trials

Clinical Trials required where:

- the Product does not fit into an existing Drug Tariff category
- the Product heralds a new treatment method
- reimbursement at a higher level than other products in the same Drug Tariff category is sought
- All trials must be carried out in line with EN540 - Clinical Investigations of Medical Devices for Human Subjects

Initial Department of Health Response

The Guidance Document reads:

22. "The Drug Tariff Section will acknowledge each application within 7 working days of receipt. Requests for additional information together with an assessment of the likely stages involved in processing the application will be issued as and when necessary."

Use of Expert Panels

- New Category of Product
- New Therapy Area
- Appropriateness
- Cost Effectiveness
- Entry Price

Drug Tariff Application Processing Statistics

Period	The number of applications:		
	New	Cleared	Outstanding
Jan - Mar '98	58	47	139
Apr - Jun '98	49	30	158
Jul - Sep '98	37	47	158
Oct - Dec '98	37	61	134
Jan - Mar '99	59	33	159
Apr - Jun '99	34	69	125

Common Pitfalls

- Information submitted inaccurate or incomplete
- Price not justified
- Clinical evidence weak
- Application made too early
  - product not fully developed
  - Technical Dossier not prepared
  - Packaging not complete
  - Production line samples not available

Role of ABHI

- Drug Tariff Forum
- Drug Tariff Committee
- ABHI/DH Negotiating Group

Recent Issues Addressed

- Price Increase Agreement
- Generic Pricing
- Statistics Format

Issues Under Discussion

- Entry Pricing for Innovative Products
- Review Committee
- Automatic Listing after deadline
- Revised Guidance Document

SUMMARY

- **The Drug Tariff lists items available on FP10 together with the price and amount payable to dispensing contractors**
- **Part IX represents just 5.34% of Drugs Bill**
- **Part IX provides manufacturers and DH with a single point for negotiation**
- **Special application process for Part IX listing**
- **The ABHI co-ordinates activity on behalf of the Healthcare Industry**

28. The Medical Devices Directive 93/42/EEC and its Relevance to Medical Textiles

D. Metcalfe

Surgical Dressing Manufacturers Association, UK

History.

Textiles have been used for medical purposes since ancient times for a wide range of applications. Similarly, standards and monographs for various dressing products have been published in Pharmacopoeias and such volumes for many years. Anyone looking at these monographs will see that they are based on the construction of the fabric rather than the performance of the product but to brush them off as irrelevant to today's needs would be unwise. If we consider simple statements for cotton gauze products such as the fabric should be clean, bleached to a good white, free from processing aids, etc, we will see that they are just as important today. Clean means that it has been scoured to remove size, and cotton wax, bleaching will remove any last traces of cotton wax and improve absorbency and washing will remove any traces of process chemicals which might otherwise leach out into the body during use.

Manufacturers of single use sterile dressings were already party to independent audits by DoH inspectors as part of the requirement for being included on the list of approved suppliers for the DoH Manufacturers Registration Scheme. However, the Medical Devices Directive brings all types of dressings within its scope, sterile & non sterile, single use and reusable products.

The Directive.

Because they had been a familiar part of every day life for so long medical textiles have been to a large extent taken for granted. The Directive focuses on two key issues:

1. **The device shall be safe.**
2. **The devices shall be fit for purpose.**

This meant that manufacturers had to look more closely at their products. Much depends on what claims they make for the product and it came as a surprise to many that their products might not even be medical devices. They could be personal protective products, they could be biocidal products or they might even be medicines.

Steps to Compliance.

Accepting that the majority of medical textile products are medical devices, there are a series of steps a manufacturer must go through before he is allowed to apply the CE mark to the product and place it on the market in the E.U. The details of what is required and some explanation of how to go about it can be found within the text of the Directive itself, the U.K. Medical Devices Regulations or in the many EN and ISO standards which have evolved in the wake of the legislation.

First of all the manufacturer must establish the intended use and means of application of the product. Then it must be classified in terms of risk as follows:

Class i	Low risk.
Class iia / iib.	Medium risk.
Class iii	High risk.

From this he can decide on a compliance route which may be adopting a quality system, type testing or a combination of these two. The options available depending on the class of product involved.

Essential Requirements.

In Annex 1, the Directive sets out a list of essential requirements which must be addressed. Manufacturers must identify those which are appropriate to a device and provide evidence to show how he intends to comply. Requirements relative to medical textile products include:

Design & construction, e.g. chemical, physical & biological properties.

Eliminate risk to patients & users.

Environmental controls, e.g. clean room activities.

sterilization controls.

packaging and labelling.

instructions for use.

Vigilance.

Suddenly the requirements of the monographs fall into perspective and perhaps they are not so out of date as some people imagine. Details of cleanliness & absence of processing aids provide support for a risk analysis. **Risk Analysis** requires the manufacturer to assess any risk the device may pose to patients and users, take steps to eliminate or minimise these risks and then where necessary provide warnings of any residual risk. Often taken for granted, this is well established in medical textiles. Take a humble gauze swab. We specify that the raw edges must be folded in - to avoid the risk of threads falling into the wound. When there was a suggestion that chlorine bleaching might give rise to the presence of dioxins, the industry switched to peroxide bleaching.

A vigilance system is simply a means of monitoring the performance of devices, collating feedback from users and customer complaints and having a recall procedure in place so that should an unforeseen problem arise, the affected batches of product can be withdrawn from use.

Compliance for Medical Textile Manufacturers.

I think that without exception, SDMA member companies opted for the quality system route utilising,

ISO 9001 / 2. and EN 46001 / 2.

together with other **appropriate standards.** This ensures that all procedures are properly documented and followed, procedures are routinely audited and all relevant records kept for the required time. Finally, when everything is in place the company can make their formal **"Declaration of Conformity"** and they are ready for inspection. All the major ISO 9000 accreditation companies have also been appointed as Notified Bodies by the Medical Devices Agency so that ISO 9000 approval and regulatory compliance can be verified at the same time. Once this approval has been granted, the manufacturer is able to affix the CE mark to the devices and place them on the market.

Manufacturers of simple class i devices do not require Notified Body approval. They can simply follow the instructions in Annex vii, send in the appropriate form to the regulatory body and apply the CE mark. However, the Competent Authorities (in UK this is the Medical Devices Agency) visit class i manufacturers, just to make sure that no-one cheats.

Benefits to Manufacturers.

A properly operated quality system will provide opportunities for problem solving and improving efficiencies. The CE mark prevents member States from introducing artificial barriers to trade and the proper application of the Directive ensures that manufacturers throughout Europe compete on an even footing.

Benefits to Patients and Users.

CONFIDENCE - knowing that devices of all types have been manufactured under stringent controls.

CONFIDENCE - to know that should something untoward occur, both the manufacturer and the Medical Devices Agency have procedures in place to warn people who may be at risk, to withdraw suspect products and to investigate the cause and prevent recurrence.

Conclusion.

The Medical Devices Directive has, then, caused manufacturers to take a closer look at their products in terms of how and where they are used than perhaps they have done for some time. They were possibly surprised to see that much of what they were already doing was what was required by the Regulations. What it has caused them to do is to formalise their activities and link them together into a management system. This should provide benefits to manufacturers, users and patients alike.

David Metcalfe.
June 1999.

Note.

Copies of European Directives and U.K. Statutory Instruments can be obtained from The Stationary Office.

British, European and International Standards are available from British Standards Institution, 389 Chiswick High Road, London. W4 4AL